FOODS

The following table displays funding and full time equivalent (FTE) staffing levels for FY 2011 through FY 2013.

FDA Program Resources Table
(Dollars in thousands)

	FY 2011		FY 2012	FY 2013	
	Enacted	Actuals	Enacted	Request	+/- Enacted
Program Level	**$835,682**	**$836,244**	**$882,747**	**$1,083,939**	**$201,192**
Center	$252,322	$252,540	$264,760	$367,622	$102,862
FTE	1,022	876	933	1,082	149
Field	$583,360	$583,704	$617,987	$716,317	$98,330
FTE	2,574	2,729	2,824	2,965	141
Program Level FTE	**3,596**	**3,605**	**3,757**	**4,047**	**290**
Budget Authority	**$835,682**	**$836,244**	**$866,061**	**$855,239**	**($10,822)**
Center	$252,322	$252,540	$264,296	$261,189	($3,107)
Field	$583,360	$583,704	$601,765	$594,050	($7,715)
Budget Authority FTE	**3,596**	**3,605**	**3,684**	**3,684**	**0**
Center	1,022	876	931	931	0
Field	2,574	2,729	2,753	2,753	0
User Fees	**$0**	**$0**	**$16,686**	**$228,700**	**$212,014**
Reinspection			**$6,825**	**$7,134**	**$309**
Field			$6,825	$7,134	$309
FTE			48	48	0
Recall User Fee			**$9,861**	**$10,308**	**$447**
Center			464	485	21
FTE			2	2	0
Field			9,397	9,823	426
FTE			23	23	0
Food Establishment Registration Fee [1]			**$0**	**$189,747**	**$189,747**
Center			$0	$89,478	$89,478
FTE			0	100	100
Field			$0	$100,269	$100,269
FTE			0	120	120
Cosmetics User Fee [1]			**0**	**16,332**	**16,332**
Center			$0	12,012	12,012
FTE			0	42	42
Field			$0	4,320	4,320
FTE			0	18	18
Food Contact Notification User fee [1]			**0**	**4,458**	**4,458**
Center			$0	4,458	4,458
FTE			0	7	7
Field			$0	0	0
FTE			0	0	0
International Courier User Fee [1]			**$0**	**$721**	**$721**
Field			0	$721	$721
FTE			0	3	3
User Fee FTE	**0**	**0**	**73**	**363**	**290**

[1] Proposed User fee; the amount includes associated rent activity

The FDA Foods Program operates under the following legal authorities:

Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 321-399)

Federal Import Milk Act (21 U.S.C. 142-149)
Public Health Service Act (42 U.S.C. 201, *et seq.*)
Food Additives Amendment of 1958*
Color Additives Amendments of 1960
The Fair Packaging and Labeling Act (15 U.S.C. 1451-1461)
Safe Drinking Water Act (21 U.S.C. 349)
Saccharin Study and Labeling Act*
Infant Formula Act of 1980*
Drug Enforcement, Education, and Control Act of 1986*
Nutrition Labeling and Education Act of 1990*
Dietary Supplement Health and Education Act of 1994*
Food Quality Protection Act of 1996*
Federal Tea Tasters Repeal Act (42 U.S.C. 41)
Safe Drinking Water Act Amendments of 1996 (21 U.S.C. 349)
Food and Drug Administration Modernization Act of 1997*
Antimicrobial Regulation Technical Corrections Act of 1998*
Public Health Security and Bioterrorism Preparedness and Response Act of 2002*
Food Allergen Labeling and Consumer Protection Act of 2004*
Sanitary Food Transportation Act of 2005*
Dietary Supplement and Nonprescription Drug Consumer Protection Act (21 U.S.C.379aa-1)*
Food and Drug Administration Amendment Act of 2007*
Patient Protection and Affordable Care Act
FDA Food Safety Modernization Act (P.L. 111-353)

Allocation Method: Direct Federal/intramural; Contract

Program Description and Accomplishments

The focus of the FDA Foods Program is to protect consumers and promote the public health by safeguarding America's food supply and empowering consumers to choose healthy diets. Outbreaks of foodborne illness and contamination events have a substantial impact on public health – 48 million foodborne illnesses occur every year resulting in 128,000 hospitalizations and 3,000 deaths.[1] The average cost per case of foodborne illness is $1,626 which resulted in an aggregated annual cost of illness of $77.7 billion[2]. These illnesses and deaths also disrupt the food system at great economic cost and undermine public confidence in the food supply.

*Authorities under this act do not appear in sequence in the U.S. Code. The authorities are codified as amended in scattered sections of 21 U.S.C.

[1] CDC. 2011. Estimates of Foodborne Illness in the United States. A comparable analysis cannot be made between CDC's 2011 estimates of foodborne illnesses and findings from earlier years due to a new methodology being used in 2011.

[2] Scharff, Robert L., "Economic Burden from Health Losses Due to Foodborne Illness in the United States," Journal of Food Protection, Volume 75, Number 1, January 2012, pp. 123-131(9).

Furthermore, the excess intake of calories, dietary fat, and sodium contribute significantly to rising rates of chronic disease, including hypertension, heart disease, stroke, diabetes, and obesity. CDC data indicate that more than 30 percent of the American adult population, approximately, 60 million people[3],is obese and that 17 percent of children and adolescents aged 2 to19 years are obese.[4]

In a dynamic and ever growing global marketplace, consumers and industry rely on FDA to continue to uphold effective safety and labeling standards. FDA is responsible for all domestic and imported food from farm to table with the exception of meat, poultry, and frozen, dried, and liquid eggs. FDA regulation takes place from the products' processing, or point of U.S. entry, to their point of sale.

FDA regulates $417 billion worth of domestic food, $49 billion worth of imported food, and $62 billion worth of cosmetics. This responsibility involves about 167,000 registered domestic food establishments, about 254,000 registered foreign facilities, and more than 3,500 cosmetic firms. FDA also promotes healthful dietary practices for American consumers by ensuring that regulated food product labels are truthful, non-misleading, and otherwise properly labeled, for example, with the Nutrition Facts Label, and by regulating the safety of food ingredients.

FDA Food Safety Strategy

Congress recognized the unique challenges faced by FDA in the area of food safety in the 21st century, and gave the agency a modern legislative mandate to meet these challenges by enacting the new FDA Food Safety Modernization Act (FSMA). FSMA directs FDA to build a food safety system based on the public health principle of comprehensive prevention, an enhanced focus on risk-based resource allocation, and partnership across the public and private sectors to minimize hazards from farm to table.

The FDA *Food and Veterinary Medicine (FVM) Strategic Plan* takes this statutory framework into account and places high priority on the prevention of foodborne illness of unknown origins and illness that can be specifically attributed to known sources.[5] Under the leadership of the Commissioner of Food and Drugs and the Deputy Commissioner for Foods, the FDA Foods Program — including the Center for Food Safety and Applied Nutrition (CFSAN) and the Office of Regulatory Affairs (ORA), with its field forces nationwide, focuses on securing high rates of compliance with science-based food safety and labeling standards by implementing integrated, prevention-oriented and risk-based programs to protect the safety and security of foods and cosmetics and to ensure that food labels contain useful and reliable information.

[3] http://www.cdc.gov/obesity/data/adult.html
[4] http://www.cdc.gov/obesity/childhood/data.html
[5] The strategic plan can be found on the FDA web site at:
http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/UCM273732.pdf

The FDA Foods Program executes its regulatory responsibilities through five sub-programs in order to achieve the goals of the *FVM Strategic Plan*:

1. Prioritizing Prevention
2. Strengthening Surveillance and Enforcement
3. Improving Response and Recovery
4. Nutrition & Labeling Strategies for Better Health
5. Reinventing Cosmetics Safety.

The first three sub-programs allow FDA to address known and unknown sources of illness across the farm-to-table continuum. *Prioritizing Prevention* resources allow FDA to establish a science-based, prevention-focused food safety system through standard-setting, industry outreach, and consumer education. Information gained from the risk analysis, regulatory science, enforcement, and response activities of *Strengthening Surveillance and Enforcement* and *Improving Response and Recovery* enables FDA to monitor the nation's food supply, identify the most significant foodborne contaminants, whether biological or chemical, evaluate the effectiveness of FDA controls for those contaminants, and take action to mitigate incidents of foodborne illness and contamination.

The remaining sub-programs allow FDA to address public health issues unique to these areas. *Nutrition & Labeling Strategies for Better Health* resources enable FDA to promote healthful dietary practices by ensuring that product labeling is informative as well as truthful and non-misleading. Lastly, FDA provides oversight of the safety of cosmetics products in the U.S. marketplace through the *Reinventing Cosmetics Safety* sub-program.

Prioritizing Prevention - Center Activities
FY 2012 Enacted Amount: $79,075,000 (All BA)

Public Health Focus

The public health focus of *Prioritizing Prevention* is to prevent food safety problems before they occur and protect the American food supply from unintentional and deliberate contamination.

FDA Food Safety Strategy

The resources in this sub-program support the *FVM Strategic Plan* goal to establish science-based preventive control standards across the farm-to-table continuum. FDA standards, guidance and industry outreach address food production and handling at the farm, processing, transportation, storage, and retail stages of the farm-to-table continuum. Outreach to consumers is the final opportunity for prevention from farm-to-table and helps consumers avoid harm from consuming contaminated food.

Prioritizing Prevention is critical to the activities of the other food safety sub-programs, as FDA uses these resources to establish the prevention-focused regulatory standards that govern the farm-to-table continuum. In turn, FDA uses the results of regulatory science, product surveillance, and risk analysis to inform standard-setting activities and focus efforts to address both known and unknown sources of foodborne illness. Enforcement and response activities, such as inspections, compliance cases, and food-related incident response, help FDA address issues that occur in the farm-to-table continuum and provide insight into areas where additional or expanded standards, controls, outreach, and education would improve food safety results.

Public Health Outcome

Driven by science and modern information technology, CFSAN develops and implements uniform, science-based standards to counter potential hazards before they harm American consumers. CFSAN FY 2012 enacted funding in this sub-program provides the resources to protect consumers and support industry through scientific and analytical tools to better identify and understand food safety risks and the effectiveness of control measures used to protect the food supply on both a premarket and postmarket basis. FDA also works with regulatory partners to strengthen and better integrate the American food safety system at the federal, state, and local levels, as well as to increase confidence that imported food is as safe as domestic.

Premarket Activities: CFSAN FY 2012 enacted programs protect the public health by assessing and evaluating the safety of infant formula prior to marketing and the safety of substances that industry intentionally adds to food and substances that may become components of food because of contact with food packaging or during food processing. CFSAN gives special priority to reviewing new ingredients, treatments, and processes that have the potential to benefit public health (e.g., through the reduction of foodborne illness by preventing or mitigating microbial contamination). Recent examples include the approval of several new preventive controls including new applications of irradiation in the treatment of food and new chemical antimicrobial treatments.

CFSAN FY 2012 enacted resources also support the development of review science to support the evaluation of submissions for new and emerging technologies and to address emerging public health challenges. Some of these include:

- food ingredients and packaging made using nanoengineered particles
- food ingredients produced from genetically engineered plants
- substances with the potential to cause allergic reactions in sensitive individuals
- substances with potential endocrine activity.

Food Ingredients and Packaging: In recent years, FDA's premarket program for food ingredients and packaging components has continued to meet its performance goals for timely review of industry submissions for premarket approval. At the same time, this program has met a number of postmarket challenges. In March 2011, FDA's Food

Advisory Committee (FAC) convened to evaluate the possible association between the consumption of synthetic color additives in food and hyperactivity in children. The Committee made the determination that relevant scientific data did not support a causal link between consumption of certified color additives in food and hyperactivity and other problematic behaviors in children. The Committee suggested that additional safety studies, such as developmental neurotoxicity testing of the color additives, be conducted and that a robust intake estimate be calculated. Additionally, 57 percent of the members of the Committee voted against additional labeling requirements for foods that contain certified color additives. FDA is currently collecting data on amounts of color additives used in food. These data will be used to estimate dietary exposure for various populations, including children. Additionally, FDA has begun a reassessment of all safety studies conducted on certified color additives that are available in its files. Based on this evaluation, FDA will determine whether and which additional safety studies are needed. CFSAN FY 2012 enacted resources also enabled FDA to remove several perfluorinated, grease-proofing compounds formerly used in food packaging from the market and take various actions to address the safety of the use of novel botanical ingredients in food.

Dietary Supplements: In July 2011, FDA issued draft guidance for the dietary supplement industry on ensuring the safety of new dietary ingredients (NDI). The draft guidance is intended to inform and assist manufacturers, distributors, and other industry entities in deciding when a premarket safety notification for a dietary supplement containing an NDI is necessary and in preparing premarket safety notifications. The draft guidance clarifies that manufacturers must notify FDA in advance when adding a new ingredient with an unknown safety profile to their products and must also provide evidence that the ingredient is safe for consumers. If the notice from a supplement firm is deemed inadequate because the new ingredient is an anabolic steroid or a material with the same chemical qualities, FDA is required by FSMA Section 113 to alert the Drug Enforcement Administration. FDA is reviewing and evaluating all comments for consideration in the final NDI guidance.

Postmarket Activities: CFSAN FY 2012 enacted programs protect the public health by providing industry with information and requirements in the form of regulations and with recommendations in the form of guidance on preventive controls. These controls help protect consumers from intentional and unintentional chemical and microbial contaminants in food products, ranging from minimally processed foods, such as fresh produce, to processed foods, such as low-acid canned foods.

FSMA-Mandated Standards: FDA announced two new regulations in May 2011, the first regulations to be issued under new FSMA authorities, that will help ensure the safety and security of food in the United States. The first rule strengthens FDA's ability to prevent potentially unsafe food from entering commerce by allowing FDA to administratively detain food that FDA has reason to believe is adulterated or misbranded. The second rule requires anyone importing food or feed into the United States to inform FDA if any country has refused entry to the same product, allowing FDA to target and prevent entry of foods that may pose a significant risk to public

health. Both rules will be followed by additional proposed rules for domestic and imported food that will help FDA continue building the new food safety system called for by Congress.

CFSAN also develops science-based safety standards to reduce risk in specific commodities and from specific pathogens. FDA released the 4th edition of the "Fish and Fishery Products Hazards and Controls Guidance" in April 2011. The guidance contains the Agency's latest recommendations to the seafood industry for reducing or eliminating food safety hazards in the fish and fishery products they process. This guidance assists processors of fish and fishery products in the development of their Hazard Analysis Critical Control Point (HACCP) plans, and helps consumers and the public understand commercial seafood safety in terms of hazards and their controls. The guidance also fulfills a requirement of FSMA Section 103 on hazard analysis and risk-based preventive controls.

Preventing *Salmonella*: *Salmonella* is the leading pathogen contributing to domestically acquired foodborne illness resulting in hospitalization and death. FDA established standards to protect consumers from *Salmonella* and save thousands of lives over the next few years:

- In July 2011, FDA published draft guidance that provides direction to egg producers and other persons who are covered by FDA's final rule "Prevention of Salmonella Enteritidis (SE) in Shell Eggs During Production, Storage, and Transportation" (74 FR 33030). The guidance responds to questions FDA received on the final rule since its publication in July 2009. The draft guidance assists egg producers in meeting required preventive measures during the production of eggs in poultry houses and refrigeration during storage and transportation.
- FDA also published a draft guidance for industry in March 2011 to address testing procedures for *Salmonella* species in human foods and direct human-contact animal foods, and the interpretation of test results, when the presence of *Salmonella* species in food may render the food injurious to human health and therefore adulterated under the Federal Food, Drug, and Cosmetic Act. FDA may take enforcement action where food tested positive for *Salmonella* species.

Bottled Water Safety: In October 2011, FDA published a final rule that established an allowable level for the chemical di(2-ethylhexyl)phthalate (DEHP) in bottled water. As a consequence, bottled water manufacturers are required to monitor their finished bottled water products for DEHP at least once each year under the Current Good Manufacturing Practice (cGMP) regulations for bottled water. This final rule will ensure that FDA's standards for the minimum quality of bottled water, as affected by DEHP, will be no less protective of the public health than those set by the Environmental Protection Agency (EPA) for public drinking water.

Retail Food Safety: The activities of the retail food safety program are prevention-focused to improve food safety practices and food equipment sanitation in retail and food service establishments.

- In September 2011, FDA established a Retail Food Safety Action Plan that includes several measures to help ensure the safety of food sold in food stores, restaurants, schools, and other foodservice operations in the United States. The Action Plan focuses on improving the way managers of these establishments conduct food safety operations in their facilities, as well as improving the oversight of these establishments by public health agencies at the Federal, state and local levels. The Plan specifically calls for strengthening state and local food safety requirements that apply to these establishments and for improving training for personnel on measures to keep food safe.

- In support of the Retail Food Safety Action Plan, FDA announced a Supplement to the 2009 FDA Food Code that includes a new and important recommendation that retail food establishments employ at least one certified food protection manager to ensure adherence to safe practices and standards within the establishment. The FDA Food Code is a set of model food-safety regulations for keeping food safe at retail and food-service operations including restaurants, schools and food stores. Local, state and tribal authorities use the Food Code to develop or update their own food safety rules to be consistent with national food regulatory policy. Keeping the Food Code current with this Supplement is part of FDA's effort to promote its full adoption and implementation by State, local and tribal authorities across the United States.

- In August 2011, CFSAN released the Employee Health and Personal Hygiene Interactive Resource Disk for use by foodservice establishments and retail food stores to prevent transmission of foodborne pathogens from sick food employees. The disk includes an interactive tool to assist supervisors of these establishments make correct decisions to prevent the sick employees from working with food, as well as several FDA resource documents. The disk is a tool that quickly provides information needed by retail food establishments to help prevent transmission of foodborne diseases.

- In October 2010, FDA issued the "FDA Trend Analysis Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurants, and Retail Food Store Facility Types (1998-2008)." The report presents results from a 10-year study on trends in practices and behaviors commonly identified by the Centers for Disease Control and Prevention (CDC) as contributing factors in foodborne illness outbreaks.

- CFSAN also launched a campaign to raise awareness of sanitation concerns and offer tips for cleaning and maintaining commercial deli slicers commonly used to sliced meats, cheeses, and produce in food stores, delis, restaurants, and other foodservice establishments. FDA was instrumental in improving the October

2010 revision of the American National Standard for the design and construction of new deli slicers.

Import Safety: CFSAN conducts prevention-oriented outreach and engages industry and foreign government partners in evaluation and harmonization of international food safety standards to ensure that imported food is as safe as that produced domestically.

- In September 2011, FDA participated in the opening of the International Food Safety Training Laboratory (IFSTL). IFSTL is the first-of-its-kind full time international food safety training facility whose primary focus is to train foreign government officials, third party laboratory scientists and food producers on fit-for-purpose microbiological and chemical analytical procedures. By partnering with the IFSTL, FDA has taken a leadership role in the international food safety community in establishing a platform to build collaboration and cooperation between regulatory agencies from many countries and the global food industry. The Laboratory will help FDA defend against contaminated food imports at the source, rather than at the border.

- In November 2011, FDA gathered information from regulators in other countries regarding the regulatory policies, practices and programs that they currently use to ensure the safety of foods and animal feed imported into their countries.

- In March 2011, FDA held a public hearing to provide stakeholders the opportunity to discuss FDA's use of international comparability assessments as a mechanism to enhance the safety of imported foods and animal feed and lessons learned through equivalence determinations. A comparability assessment determines whether foreign countries have comparable food safety systems or robust commodity specific export programs similar to those in the United States.

- FDA reviews draft food safety and labeling laws and regulations sent to the World Trade Organization (WTO) by its members, known as WTO notifications. Experts at CFSAN examine these proposed regulations for scientific coherence, feasibility, and potential to impact public health if implemented as written. CFSAN comments are then incorporated into official United States comments sent to the WTO member proposing the given regulation. During 2011, CFSAN reviewed nearly 400 draft rules and regulations through the foreign WTO notification review process.

Food Defense: FDA continues to be active in implementing food defense strategies that help protect the nation's food supply from deliberate acts of contamination or tampering.

- In March 2011, FDA released the Food Defense Mitigation Strategies Database (MSD), one of several tools developed by FDA for the food industry. This online resource is designed for companies that produce, process, store, package, distribute, and/or transport food or food ingredients to aid them in conducting vulnerability assessments and determine suitable mitigation strategies. The

MSD provides a range of preventive measures that companies may choose to implement to better protect their facility, personnel, products, and operations.

- CFSAN partnered with USDA's Foreign Agricultural Service to implement a Food Defense International Outreach Strategy to build relationships, raise awareness and provide training on food defense planning. The team completed food defense programs, trainings, and "roadshows" in Mexico, China, the Philippines, Turkey, Kyrgyzstan, Tajikistan, Uzbekistan, and Kazakhstan. These efforts resulted in foreign government efforts to conduct vulnerability assessments, establish food defense interagency working groups, develop industry guidance, add food defense to academic curricula, and develop and implement food defense plans by industry participants in each of the countries impacted to date.

Outreach and Education: FDA conducts outreach and education to consumers, industry, and other public health agencies to promote better understanding of food safety practices and implementation of FSMA provisions. As a result, industry, consumers, and public health partners are better able to prevent foodborne contamination and illness.

- CFSAN partnered with the National Science Teachers Association (NSTA) to establish the FDA Teachers Academy in Food Science and develop web-based tutorials in Science for Food Safety and Nutrition for middle and high school science teachers. The program provides challenging hands-on activities that link food safety to students' everyday lives, covering food science from the farm to the table in a format linked to the National Science Education Standards.

- FDA also released several informative new food and feed safety videos on the "FDA You Tube" page. FDA offers these videos in seven foreign languages as a service to a broad international audience. These videos include: "Regulatory Approaches to Dietary Supplements and their Claims," "Reportable Food Registry," and "LACF [Low-Acid Canned Foods] and Acidified Foods Regulations and Requirements."

- In FY 2011, FDA held a public meeting on FSMA preventive controls for facilities, a public meeting on FSMA import safety, and a public hearing on comparability of food safety systems and import practices of foreign countries. These meetings and hearing provided a forum for FDA and the public to exchange information and share views that will aid in the development of regulations and guidance documents.

- FDA also redesigned its web page dedicated to FSMA to make it easier for consumers, industry, food safety professionals, local and state regulators, and international trading partners to obtain the latest information about FSMA and become involved through public hearings. The site consists of more than 200 web pages of information and fosters food safety awareness by aggregating links to the full text of the FSMA law which is translated into 11 languages, and

includes frequently asked questions, consumer updates, tools and resources developed by FDA, videos from FDA food safety experts, the FSMA implementation plan and progress updates, and outreach invitations and transcripts of public meetings.

Promoting Efficiency

Preventing a single fatal case of *E. coli* O157 infection saves an estimated $7 million dollars.[6] The activities in *Prioritizing Prevention* help to prevent the overall negative economic impact of foodborne illness to the economy by providing guidance to industry about safe food products and packaging. As a result, FDA protects consumers from foodborne illness and helps industry avoid the risk and expense of recalling products that do not meet safety standards.

Each year, CFSAN provides more than 100 consultations to assist industry with specific guidance to firms on how to best address safety questions relating to food ingredients and packaging. *Prioritizing Prevention* premarket review activities alert industry to potential problems with new ingredients, labeling, and infant formula. CFSAN also expedites the premarket review of FDA-regulated food ingredients and packaging, processing aids such as antimicrobials used to mitigate food contamination, and sources of irradiation that may have potential food safety benefits. These FDA activities help industry to:

- avoid potential safety problems and associated recalls
- more efficiently introduce new or changed infant formulas
- decrease the costs of innovation for food safety
- speed the entry of safe food products and technologies to market.

CFSAN also promotes the development of international, science-based, Codex product standards. Codex standards help ensure that food imports meet U.S. regulatory standards to protect American consumers, while also promoting fair trading practices that are important to the food industry.

Prioritizing Prevention - Field Activities
FY 2012 Enacted Amount: $111,373,000 (All BA)

Public Health Focus

ORA's top priorities for advancing public health and protecting consumers focus on:

- prevention through outreach coordination and technical assistance to industry
- internal and external training, which increases expertise and encourages collaboration with external stakeholders

[6] http://www.cdc.gov/foodsafety/cdc-and-food-safety.html

- preventive controls in the food supply chain from the point of production to delivery into the U.S. supply chain.

FDA Food Safety Strategy

The conference agreement on the FY 2012 FDA appropriation asks FDA to articulate its food safety strategy in the FY 2013 budget and tie the FY 2013 FDA budget request for food safety to the FDA food safety strategy. A summary of the strategy appears in the Transforming Food Safety business case paper in the Executive Summary of this budget document. The full strategy can be found at the following FDA web link: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/UCM273732.pdf

In the case of the Prioritizing Prevention, ORA contributes to achieving the overall FDA strategy by focusing more on preventing food safety problems rather than relying primarily on reacting to problems after they occur and implementing the provisions of FSMA is through the development of regulations, standards and guidance documents. These activities are reflected within the draft FDA Foods and Veterinary Medicine (FVM) Program Strategic Plan goal of establishing science-based preventive control standards across the farm-to-table continuum. This includes the adoption of science-based regulations that protect the food and feed supply from contamination, including the identification of the most significant foodborne contaminants and an evaluation of the effectiveness of existing controls for those contaminants.

Public Health Outcome

In 2011, ORA participated in outreach events at a variety of public meetings, symposiums, and conferences that are attended by regulated industry, other government agencies, and foreign regulatory bodies.

The FDA Compendium of Microbiological Protocols and Chemical Tests (COMPACT), a compilation of analytical detection methods for foods designed to support the mission of FDA was released in the Electronic Laboratory Exchange Network (eLEXNET). COMPACT serves as the primary resource in support of emergency analytical needs such as large-scale food-borne outbreak and food safety surveillance activities. eLEXNET added six new laboratories in FY 2011.

FDA began regulating firms under 21 CFR 118, better known as the Egg Safety Rule in FY 2010. Since then, ORA has conducted more than 450 inspections and collected over 150 samples including over 2,000 environmental swabs. Of the samples collected by ORA, 22 were found positive for Salmonella Enteriditis. ORA took several regulatory actions including issuance of warning letters, untitled letters, and a voluntary recall. ORA works with industry to help ensure their response measures are appropriate within the regulation, including re-inspection of firms to determine their compliance status. ORA participated in industry outreach programs with the egg producing industry, providing education on compliance with the Egg Safety Rule.

FDA analyzes trends in the regulated marketplace to assure the safety of regulated

commodities before there is a public health issue. FDA identified one such challenge related to caffeinated alcoholic beverages. ORA collected numerous samples and analyzed the products for the presence of caffeine. The analytical findings led to the issuance of several warning letters to manufacturers of these beverages offered for sale at retail locations throughout the nation, and subsequently, to cessation of marketing.

ORA awarded funds to associations under the Small Scientific Conference Grant and to state and local regulatory agencies under the Food Protection Task Force Grant. These grants provided the resources to foster communication and collaboration on a range of topics, including food safety, food security and protection, intervention, and prevention through the review of food supply vulnerabilities.

FDA developed and is currently implementing a new strategy, in collaboration with Customs and Border Protection (CBP) and Immigration and Customs Enforcement (ICE) under the Department of Homeland Security (DHS), to better prevent the entry of smuggled food/feed into the U.S., fulfilling the requirement of FSMA Section 309(a). When smuggled food/feed goes unexamined by regulators, it presents a hazard to consumers and erodes confidence in the safety of the food/feed supply. A comprehensive strategy to combat the entry of smuggled food/feed helps to protect the public health. FDA is working closely with CBP to target and examine import shipments that could conceal undeclared foods/feeds, focusing on high risk parties and imported foods/feeds that pose a significant public health risk.

FDA awarded seven grants to enhance the ability of the grantee to design, develop, and deliver food safety training and personnel certification programs by leveraging the expertise of universities, professional trade associations, and non-profit organizations. The primary focus of the awardee and FDA collaborative venture is to design, develop, and disseminate food and feed safety training programs that are consistent with the Manufactured Food and Retail Food Regulatory Program Standards, as well as third party criteria for accreditation. This venture will emphasize public health safety according to the needs of FDA and our regulatory and public health counterparts, while also fostering the development of a network of food safety professionals. FDA aims to establish a fully integrated food safety system (IFSS) that will place priority on preventing foodborne illness through the adoption and uniform application of model programs.

Promoting Efficiency

ORA conducts outreach to ensure transparency, open communication, and sharing of information and ideas with consumers, regulated industry, and the import trade community. Prioritizing Prevention activities help anticipate and prevent food safety problems, which generates efficiencies for industry, consumers, and FDA. In addition to protecting public health, prevention leads to efficiencies and savings for consumers and industry by avoiding the expenses associated with contaminated foods.

ORA offers training to its state partners in conducting inspections of egg producers, low acid canned food manufacturers and seafood processors. By providing this training, FDA/ORA is strengthening the infrastructure of state inspection programs and furthering the implementation of an integrated food safety system.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
213301: Complete review and action on the safety evaluation of direct and indirect food and color additive petitions, within 360 days of receipt. (*Output)*	FY 2010: 100% Target: 70% (Target Exceeded)	80%	80%	Maintain
214101: Number of state, local, and tribal regulatory agencies in the U.S. and its Territories enrolled in the draft Voluntary National Retail Food Regulatory Program Standards. *(Outcome)*	FY 2011: 485 Enrolled Target: 362 Enrolled (Target Exceeded)	502 Enrolled	519 Enrolled	+17 Enrolled
212404: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Campylobacter* species. (*Outcome)*	CY 2009:12.9 cases/100,000 (Historical Actual)	11.9 cases/ 100,000	11.7 cases/ 100,000	-.25 cases/ 100,000
212405: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: Shiga toxin-producing *Escherichia coli* O157:H7. (*Outcome)*	CY 2009: 1.0 cases/100,000 (Historical Actual)	1.09 cases/ 100,000	1.04 cases/ 100,000	-.05 cases/ 100,000
212406: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Listeria monocytogenes*. (*Outcome)*	CY 2009: 0.30 cases/100,000 (Historical Actual).	.29 cases/ 100,000	0.28 cases/ 100,000	-.01 cases/ 100,000
212407: Reduce the incidence of infection caused by key pathogens commonly transmitted by food: *Salmonella* species. (*Outcome)*	CY 2009: 15.0 cases/100,000 (Historical Actual)	14.5 cases/ 100,000	14.2 cases/ 100,000	-.30 cases/ 100,000
212409: Reducing foodborne illness in the population. By December 31, 2013, decrease the rate of Salmonella Enteritidis (SE) illness in the population from 2.6 cases per 100,000 (2007-2009 baseline) to 2.1 cases per 100,000. (*Outcome*)	FY 2009: 2.6 cases/100,000 (Historical Actual: average rate of SE illness: 2007 to 2009)	2.2 cases/ 100,000	2.1 cases/ 100,000	-0.2 cases/ 100,000

Strengthening Surveillance and Enforcement - A. Strengthening Surveillance - Center Activities
FY 2012 Enacted Amount: $118,770,000 (All BA)

Public Health Focus

The public health focus of *Strengthening Surveillance* is to assess and communicate the specific risks associated with food products to American consumers and industry on a routine basis, as well as during foodborne illness outbreaks or cases of chemical contamination.

FDA Food Safety Strategy

The resources in this subprogram support the *FVM Strategic Plan* goals to strengthen scientific leadership, capacity, and partnership to support public health decision making and to improve effectiveness and efficiency across all levels of the food safety system. FDA evaluates risk and conducts surveillance of the nation's food supply to monitor and evaluate the safety and effectiveness of the food safety system across the farm-to-table continuum. Likewise, FDA regulatory science projects improve the Agency's ability to detect both known and unknown pathogens and better understand potential hazards. These activities inform the use of resources across all subprograms, allowing FDA to target inspections and standard-setting activities to best address known and emerging food safety concerns.

Public Health Outcome

CFSAN's FY 2012 enacted activities for this sub-program center on the use of food safety surveillance information and scientific data and tools to prevent illness and injury from foods. These FY 2012 enacted activities also protect American consumers from harm by improving understanding of the sources of foodborne outbreaks and cases of intentional or unintentional chemical contamination, as well as the ability of the Agency to detect these types of issues in the food supply.

Postmarket Surveillance: A significant focus of CFSAN's FY 2012 enacted activities is using postmarket surveillance information and scientific methods and tools to identify and monitor food products that pose a threat to public health. For example, CFSAN contracted with IEH Laboratories to complete testing of 8,139 leafy green vegetables (spinach, iceberg lettuce, and romaine lettuce) for *Salmonella*, *Shigella* and *E. coli* in one year. This surveillance detected five *Salmonella* and two *E. coli* positive samples, resulting in five recalls that removed these adulterated products from the marketplace.

CFSAN, along with other FDA components, is working to develop adverse events early warning systems that can integrate and mine data rapidly to detect real-time signals of adverse events or consumer complaints associated with regulated products. The Reportable Food Registry (RFR) is one such improved early warning system, where food processors must report the possibility of food contamination. These reports trigger

rapid FDA and state response to determine and stop the cause before people become sick. In January 2011, FDA issued the first annual report on the RFR entitled, "A New Approach to Targeting Inspection Resources and Identifying Patterns of Adulteration," covering results from September 2009 to September 2010.[7] The report shows that, in its first year, the RFR significantly strengthened the ability of FDA to track patterns of food and feed adulteration and target inspection resources to identify adulterated food/feed and prevent foodborne illnesses. The report demonstrates the Agency's success in receiving early warning on problems with food and feed through surveillance functions to better protect the public health.

Risk Analysis and Assessment: Funding for CFSAN's FY 2012 enacted activities also supports improving the availability of chemistry and toxicology information for better safety and risk assessments and more rapid response to episodes of food contamination. For instance, outbreaks of *E. coli* infections have been a continuing food safety challenge for the produce industry. CFSAN conducted several studies to determine how to minimize microbial cross- contamination during postharvest washing of fresh produce and to rapidly detect *E. coli* in fresh produce processing water. CFSAN also analyzed the gene function and survivability of *E. coli* from outbreaks associated with fresh produce. The tools and detection methods resulting from these studies will benefit both industry and regulators.

CFSAN FY 2012 enacted resources are currently supporting evaluations of gluten and several allergens, such as peanuts, eggs, and milk, in light of reports of adverse effects due to unintentional contamination of foods during food processing. CFSAN completed several scientific studies to evaluate sensitivity and specificity of current detection methods, develop new detection methods and preventive controls, improve the harmonization of international standards for validation of allergen detection methods, validate the effectiveness of cleaning procedures, and explore prevention and treatment options for food allergens.

Protecting food from intentional contamination is also a priority of *Strengthening Surveillance*. Understanding the risks and vulnerabilities for intentional contamination in the food production, processing, and distribution system strengthens the food supply against targeting for intentional contamination. The adulteration of important commodities such as gluten and milk with melamine is an example of the food safety risk posed by economic fraud. In FY 2011, CFSAN developed a new analytical method to determine the presence of six melamine substitute compounds using liquid chromatography mass spectrometry for the rapid, sensitive, and specific detection of these adulterants. CFSAN also conducted a risk assessment for intentional contamination of food and food ingredients with melamine.

In FY 2011, CFSAN expanded vulnerability and risk assessment capabilities by developing new public tools and collaborating with other federal agencies. FDA launched a new risk assessment website to provide public information on assessing risks and completed, current and planned FDA projects, and to request public input.

[7] http://www.fda.gov/downloads/Food/FoodSafety/FoodSafetyPrograms/RFR/UCM220280.pdf

The website responds to the Institute of Medicine's call for greater visibility and transparency and informs the public that FDA not only responds to emergencies but also acts to prevent such events.

In addition, FDA actively participated in the Interagency Risk Assessment Consortium (IRAC) with 18 other federal agencies and subagencies. IRAC is chartered to address the needs identified by the President's Food Safety Working Group. IRAC collaborated with the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) to identify updates to risk models for *Listeria monocytogenes* to reflect new data and methods. FDA is also collaborating with the USDA Food Safety and Inspection Service (FSIS) and CDC to update the 2003 quantitative assessment of the relative health risk from *Listeria monocytogenes* in 23 categories of ready-to-eat foods and develop models that predict optimal interventions for reducing listeriosis. Human listeriosis is one of the major foodborne bacterial infections causing 1,600 illnesses and 250 deaths per year in the U.S. The disease specifically affects pregnant women, the elderly and the immuno-compromised population.

Rapid-Detection Technologies: Another significant focus of CFSAN'sFY 2012 enacted activities is developing and validating new, rapid-detection technologies capable of identifying contamination that leads to foodborne illness. Current test methods require anywhere from several days to weeks to deliver results, which severely limits the ability of the FDA to respond to outbreaks and emergencies and to complete timely surveillance activities. For example, the current Salmonella Enteritidis (SE) analysis for whole shell eggs can take over two weeks. CFSAN initiated development of a new rapid-detection method using molecular serotyping on cultural isolates to reduce the time for confirmed results from two weeks to five days.

In September 2011, FDA launched two pilot projects that will evaluate methods and technologies for rapid and effective tracing of foods, including types of data that are useful for tracing, ways to connect the various points in the supply chain, and how quickly the data are made available to FDA. After the pilots are completed and additional data is gathered, FDA will initiate rulemaking on recordkeeping requirements for high-risk foods to facilitate tracing. FDA continues to explore ways to use novel technologies, such as Geographic Information Systems (GIS), to improve timely surveillance activities and FDA's ability to determine the source of foodborne contamination.

CFSAN also developed the following new, science-based, rapid-detection technologies in FY 2011 that provide information critical for quicker decision making in cases of foodborne illness or product contamination, as well as for rapid risk assessments:

- An *in vitro* high-throughput screen to detect and analyze potentially toxic substances such as heavy metals, botanicals, dietary supplements, Gulf oil dispersants, nanoparticles, and microbial and biological toxins such as the botulinum toxin and marine seafood toxins. These screens are faster, less

expensive, and are being tested for their ability to provide an alternative to current animal testing.

- A custom-designed multi-virus DNA microarray (second generation) for identification of the hepatitis A virus genotype, norovirus genogroup, and coxsackievirus serotypes. This tool helps link viral outbreaks, leading to earlier detection and identification of viruses, earlier recalls, and prevention of further illnesses.

- A serotyping scheme using a combination of an antibody-based serogrouping method and a multiplex PCR assay for identifying the major serotypes of *Listeria monocytogenes*. This method identifies the serotypes of major diseases causing *L. monocytogenes* within three to four hours and can be incorporated into FDA's regulatory analysis of food samples immediately, so that contaminated samples will be more rapidly identified and removed from the shelves, preventing further illnesses from the outbreak.

- A suite of new technologies that can be applied to outbreak analysis of enteric foodborne bacteria, such as *E. coli* and *Shigella*, with a focus on establishing important food-clinical linkage attributes. Collectively, these advancements improve food safety and may reduce economic impacts to the food industry by providing enhanced tools that redefine molecular epidemiology for traceback and source-tracking.

Using these methodologies, CFSAN is able to provide results more rapidly on a wider range of regulated products.

Promoting Efficiency

CFSAN promotes efficient food safety research and development while minimizing the cost to industry to respond to food safety concerns. CFSAN uses its regulatory expertise to perform a unique coordinating role to develop and lead important collaborations with industry. Industry relies on CFSAN to provide uniform methods and establish standards to detect food contaminants and conduct analysis of nutrients. These methods and standards promote food safety improvement and a robust and stable business environment.

CFSAN also provides essential science-based information that allows industry to efficiently and effectively respond to concerns about new chemical and microbial food safety threats – including acrylamide, perchlorate, benzene, BPA, *Cronobacter sakasakii*, and *Salmonella* – and food defense-related pathogens, such as *Clostridium botulinum* toxin. CFSAN works to quickly develop and validate methods to detect such contaminants and determine their levels in food. Likewise, CFSAN collaborates with industry to develop novel technologies to detect new and traditional foodborne contaminants.

Strengthening Surveillance and Enforcement - A. Strengthening Surveillance – Field Activities
FY 2012 Enacted Amount: $286,953,000 (All BA)

Public Health Focus

To strengthen food defense/safety, surveillance and risk analysis, ORA conducts:

- import prior notice and entry reviews
- import field exams
- import sample collections
- domestic product reconciliation examinations
- laboratory analyses including sample analysis, product testing and methods development

These activities serve to minimize consumers' risk of exposure to adulterated food products by detecting and preventing the marketing of unsafe products, removing products from the market, or ensuring that products do not reach the U.S. market. Early detection of contaminated or adulterated food products and their ingredients continues to be a priority within ORA.

Activities conducted on entries offered for import into the U.S. are driven by risk-based and intelligence gathering activities that assist in identifying entries posing the highest risk to the consumer. Surveillance inspections are conducted to assess the manufacturing of products for compliance with established regulatory requirements to protect public health. Domestic product reconciliation examinations are conducted to assure manufacturers have programs in place to ensure the safety of products received for processing and also to guard against unknown individuals entering manufacturing facilities. These activities are both food defense and food safety measures.

ORA advances regulatory science by increasing the breadth of its analytical capacity and capability, while improving laboratory efficiencies and outputs. One way ORA accomplishes these advances is through the continued development of laboratory methods to detect emerging microbiological, chemical or radiological contaminants of public health concern.

FDA Food Safety Strategy

In the case of the Strengthening Surveillance, ORA contributes to achieving the overall FDA strategy by establishing a structure to enhance risk-based decision making, developing metrics and goals for risk-based food safety priority setting, and a model for evidence-based resource planning. This includes maintaining and strengthening mission-critical science capabilities, improving centralized planning and performance

measurement, and improving information sharing internally and externally including effective communication of research plans and knowledge gaps.

Public Health Outcome

In FY 2011, ORA continued its usage of the Chemistry and Microbiological Mobile Laboratories in support of FDA's food defense initiatives and surveillance of import and domestic produce. In support of FDA's continued surveillance related to the recovery mission from the Deepwater Horizon Oil Spill, the chemistry mobile laboratory was deployed to Dauphin Island, Alabama and analyzed about 1,000 finfish, shrimp and oyster samples for polycyclic aromatic hydrocarbons (PAHs). The microbiology mobile laboratory was re-deployed from a surveillance assignment in Salinas, California to Otay Mesa, California to support the 100 percent sampling and testing of Mexican Papayas implicated in an outbreak over the early late spring/early summer of 2011.

ORA and state regulatory partners under contract with FDA continued the use of environmental sampling during domestic, high-risk food facility inspections to assess the environmental conditions in which products are manufactured. These environmental samples are critical in identifying areas of concern within the production environment that have or could lead to product contamination. As a result of FDA's efforts, industry has taken many actions to recall or destroy products that were manufactured under such conditions.

For example, ORA inspected 127 soft cheese manufacturers under an assignment designed to determine the environmental conditions of these establishments. More than 10,500 environmental swabs were collected to determine the presence of *Listeria monocytogenes* in the establishments. Violative analytical findings led to voluntary recalls by the affected establishment and further regulatory actions including a product seizure.

Through implementation of Memoranda of Understanding (MOUs) with the Occupational Safety and Health Administration (OSHA) and the USDA Agricultural Marketing Service (AMS) and USDA Food Safety Inspection Service (FSIS), FDA is leveraging resources and sharing information in a way that is expected to result in the reporting of egregious food processing conditions that might otherwise go unidentified until an inspection is conducted.

ORA increased the efficiency and effectiveness of import entry review through the nationwide implementation of Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT). This system gathers intelligence from various sources, analyzes available data, cross-matches data looking for anomalies, and enables ORA to target its resources in a more strategic manner. ORA's implementation of PREDICT allows for the expedited clearance of low risk products while allowing ORA to focus examination and sample collection resources on higher risk food products.

In FY 2011, ORA continued its efforts to improve the reliability of foreign food facility registrations by continuing a contract to perform on site firm verifications of foreign food facilities to confirm the existence of the facility and to verify the information supplied in the registration. As a result of the information obtained under these efforts, FDA initiated for-cause inspection of facilities, added facilities to import alert where the manufacturing capabilities were not what was purported in the registration, and increased targeting and review of prior notice submissions to ensure accurate data is submitted.

The ORA Prior Notice Center (PNC) exceeded the 80,000 prior notice review performance measure in FY 2011. PNC conducts targeted biosecurity analysis of food entries to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food-related emergencies.

In FY 2011, ORA funded a pilot program for further deployment of the handheld portable analytical tools that were evaluated in FY 2010. These portable analytical tools are used in the early detection of contaminated food products further back in the supply chain. Portable tools return analytical screening results within minutes of implementing the test, providing ORA field personnel with data to assist in setting collection priorities based on emergent risk profiles. The first tier of tools was deployed to several ORA field offices in FY 2010. They are the first in a series of portable analytical tools that were deployed to ORA field investigators to screen certain commodity/analyte combinations. The second wave of deployments of portable analytical tools took place in FY 2011 and included tools to check for the presence of undeclared active pharmaceutical ingredients in dietary supplement products, heavy metals in food products, and diethylene glycol substituted for glycerin.

Promoting Efficiency

FDA field operations are establishing high throughput laboratories for analyzing food samples. These laboratories will allow ORA to analyze a greater volume of food samples in less time. Through this analysis, FDA can better protect consumers, make more timely regulatory decisions, and reduce the impact on regulated industry. These efforts not only provide greater assurance that foods are safe, they also maintain the efficient flow of trade. In addition, high throughput laboratories protect the public by identifying product adulteration and environmental contamination. With this analysis, FDA and industry can efficiently address such problems and allow a firm to resume business operations as quickly as possible after correcting the food safety problem.

The field operations of the Strengthening Surveillance subprogram allow ORA to identify, validate and implement new technologies to more readily detect adulterated food imports. These technologies prevent adulterated imported food from reaching U.S. consumers and allow FDA to more efficiently maintain the flow of commerce in foods that FDA regulates.

In FY 2011, FDA funded the electronic Laboratory Information Management System (LIMS) for implementation into the field laboratories over a five year period. LIMS

directly supports management through automation of analytical processes, data collection from instrumentation, chain of custody, calibration, reagent and inventory tracking, accreditation support, reporting, trending, and general laboratory management. The project entails the development of and licenses for software, commercial off the shelf product, the purchase of equipment and lab hardware, and improvements to the server and network infrastructure. LIMS will be piloted in 4 labs in FY 2012 followed by implementation into 14 static and 2 mobile ORA laboratories over an additional four years.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
214306: The average number of working days to serotype priority pathogens in food (Screening Only) (*Output)*	FY 2011: 7 working days Target: 9 working days (Target Exceeded)	6 working days	5 working days	-1 working days
214207: The number of self assessments completed by participating countries to determine whether their level of food safety oversight is comparable to the level of food safety oversight of the FDA. (Outcome)	NA	5	9	+4
214201: Number of prior notice import security reviews. *(Output)*	FY 2011: 88,057 Target: 80,000 (Target Exceeded)	80,000	80,000	Maintain
214202: Number of import food field exams. *(Output)*	FY 2011: 201,406 Target: 160,000 (Target Exceeded)	160,000	160,000	Maintain
214203: Number of Filer Evaluations. *(Output)*	FY 2011: 1,212 Target: 1,000 (Target Exceeded)	1,000	1,000	Maintain
214204: Number of examinations of FDA refused entries. *(Output)*	FY 2011: 11,789 Target: 7,000 (Target Exceeded)	7,000	7,000	Maintain
214206: Maintain accreditation for ORA labs. *(Outcome)*	FY 2011: 13 labs Target: 13 labs (Target Met)	13 labs	13 labs	Maintain

Strengthening Surveillance and Enforcement - B. Strengthening Enforcement - Center Activities

FY 2012 Enacted Amount: $25,095,000 (All BA)

Public Health Focus

The public health focus of *Strengthening Enforcement* is to prevent illnesses resulting from contaminated foods by targeting inspections and sampling and by focusing resources where they will have the greatest public health benefit.

FDA Food Safety Strategy

The resources in this subprogram support the *FVM Strategic Plan* goal to achieve high rates of compliance with preventive controls standards domestically and internationally. FDA conducts domestic and foreign inspections and leverages partner public health agencies' efforts to assure that both domestically-produced and imported foods meet preventive controls standards throughout the production and handling stages of the farm-to-table continuum. Inspections, field examples, and sample collection help FDA identify and address food safety risks, either in cooperation with industry or through enforcement actions. These activities further provide information for FDA on areas where standards and outreach are working effectively and where additional efforts are required to strengthen the food safety system, including research and risk analysis on sources of foodborne contamination.

Public Health Outcome

CFSAN FY 2012 enacted activities in this subprogram area concentrate on identifying, evaluating, and implementing risk-based programs to direct inspections, collect samples, and conduct sample analyses and field exams for the domestic and imported food supply. These efforts allow FDA to protect consumers and achieve the public health objective of preventing illnesses resulting from contaminated foods.

Risk-based Foreign Inspections: In FY 2011, CFSAN participated in the planning and coordination of more than 1,000 foreign inspections. These inspections are vital to ensure imported food is safe for American consumers. FDA also continues to conduct field assignments directing the collection and analysis of environmental samples in domestic food production facilities. In general, the purpose of these assignments is to determine if pathogens are present in the food processing environment. An annual risk-based strategy targets several commodities of interest in order to track and trend data as an indicator of industry compliance. Recent target industries included egg farms, dried spices, ready-to-eat (RTE) sandwiches, and smoked salmon processors. Under specific assignments in FY 2011, FDA collected nearly 12,000 environmental sub-samples from 156 facilities. Of these samples, 226 positives were found in 38 facilities resulting in eight compliance actions.

FSMA Enforcement Authorities: With the passage of FSMA, FDA received several new authorities designed to improve its ability to ensure that food for U.S. consumers is safe.

- In August 2011, FDA first used its administrative detention authority under FSMA to detain an order for spices, tamarinds, and chili products at a food storage warehouse after inspectors found evidence of live and dead insects in food products. The detention order resulted from inspections of the warehouse in July and August 2011. The company was previously issued a Warning Letter in April 2011, based on an inspection in early January that found evidence of rodent and insect infestation. Before this new rule, FDA would often work with state agencies to embargo a food product under the state's legal authority until federal enforcement action could be initiated in federal court. In keeping with other provisions in FSMA, FDA will continue to work with state agencies on food safety and build stronger ties with those agencies.

- In May 2011, FDA implemented a second enforcement authority that requires importers of food and feed into the U.S. to inform FDA of any country that had refused entry to the same product. This authority provides the Agency with more information about imports and allows for risk-based targeted inspections. FDA will administer the new reporting requirement through its prior notice system for incoming shipments of imported food, which was established under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. With prior notice, in the event of a credible threat for a specific product or a specific manufacturer or processor, FDA will mobilize and assist in the detention and removal of products that may pose a serious health threat to humans or animals. This new authority also allows FDA to make better informed decisions in managing the potential risks of imported food.

- In addition to the above, FDA now has the authority to prevent the distribution of unsafe food by suspending the registration of the processing facility. Food producing firms must be registered with FDA to market their products in the U.S. As required by FSMA, food facilities must have a written preventive controls plan that spells out potential safety problems and the steps that would be taken to prevent or minimize the likelihood of these hazards occurring. The registration could be suspended if the food processor not only fails to produce safe foods, but also takes no measures to keep those foods from reaching consumers. In addition to preventing their distribution, the processor of unsafe foods is expected to investigate what went wrong and take steps to prevent a recurrence. If this is not done, FDA may take enforcement action as appropriate.

Caffeinated Alcoholic Beverages: CFSAN continues to assess and act on emerging risks to public health resulting from new uses of food ingredients already in the market. In FY 2011, FDA responded to reports of hazardous and life-threatening behaviors following the consumption of caffeinated alcoholic beverages. CFSAN led an agency-wide enforcement effort that resulted in the issuance of Warning Letters to four companies producing these products. FDA also liaised with other stakeholder-agencies, including the Alcohol and Tobacco Tax and Trade Bureau, the Federal Trade Commission, and the Centers for Disease Control, on legal issues surrounding these

beverages and to raise public awareness of the potential risks of consumption. As a result of FDA's efforts, all four companies withdrew their products from the marketplace.

Dietary Supplements: In addition to food products, FDA also regulates dietary supplements and took several actions to ensure that manufactures are performing the proper controls during manufacturing, packaging, labeling, and holding operations. In November 2011, the Department of Justice, on behalf of FDA, filed the first permanent injunction citing the dietary supplement Good Manufacturing Practice (cGMP) Final Rule FDA 21 CFR Part 111. The injunctive relief sought by the government would permanently prohibit the dietary supplement manufacturer from the making and distributing of their 400 products in the United States. In addition to "adulterating" and "misbranding" their final products, the manufacturer and its owner failed to report serious adverse events such as spikes in blood pressure, hospitalization and a subsequent mild heart attack associated with their products.

Other notable enforcement actions that occurred in 2011 includes the seizure of 2.3 tons (U.S.) of extracts containing ephedrine alkaloids in California, a seizure for cGMP violations and illegal claims in Wisconsin, and a seizure for making unsubstantiated disease claims in Minnesota.

Promoting Efficiency

By identifying food safety risks through inspections and by removing unsafe or substandard products from the market, FDA protects consumers and also supports industry efforts to produce safer foods. FDA enforcement actions may also allow firms to avoid the potential high costs that result from consumer illness or injury caused by contaminated foods.

Strengthening Surveillance and Enforcement - B. Strengthening Enforcement - Field Activities
FY 2012 Enacted Amount: $167,081,000 (BA: $ 150,859,000 / UF: $16,222,000)

Public Health Focus

One of ORA's main food safety duties is to perform risk-based inspections of food producers and provide strong, effective, and efficient enforcement of FDA laws and regulations.

The safety of our nation's food supply continues to be a top priority for regulatory agencies. ORA views state-based contracts, grants, and cooperative programs, such as the Food Inspections Contracts, as important mechanisms for providing increased enforcement activities through an enhanced integrated food safety system.

FDA Food Safety Strategy

In the case of the Strengthening Enforcement, ORA contributes to achieving the overall FDA strategy by conducting risk-based domestic and foreign food safety inspections, implementing new enforcement tools, improving mechanisms for assuring that imported foods and feeds meet preventive controls standards, and improving the collaboration with state, local, tribal and territorial officials and staff on inspection and compliance efforts.

Public Health Outcome

- ORA investigators conduct on-site inspections of regulated domestic and foreign food establishments
- ORA initiates enforcement actions to address violations of our public health laws and regulations.

In FY 2011, ORA performed 1,000 foreign food establishment inspections representing an increase of 640 foreign food inspections over FY 2010, and increased the overall number of foreign inspections by 54 percent. FDA uses risk factors to target firms to inspect, focusing on-site inspections in the most critical areas, and leveraging the work of our dedicated foreign inspection cadre. This includes the FDA inspection staff located at FDA's foreign offices and our district-based investigators that enhance overall coverage of the foreign establishment inventory.

The ORA Dedicated Foreign Food Cadre alone conducted 470 foreign food inspections that resulted in nine foreign establishment Warning Letters, twelve establishments being placed on Import Alert, and five foreign manufacturers voluntarily recalling their products from the U.S. market. Additionally, implementing new statutory authority provided under the Food Safety Modernization Act, two foreign food firms were placed on import alert for refusing to allow FDA to inspect their facilities.

ORA continued to protect U.S. citizens from unsafe products of foreign origin by issuing over 800 notices that extended import controls to products and establishments related to concerns that include *Salmonella*, pesticides, and non-permitted or undeclared food additives violations.

ORA awarded multiple food inspection contracts to State Agencies and territories. These contracts enhance an integrated food safety system by providing states and territories with funding to perform basic Good Manufacturing Practices (GMP) inspections. The contracts include a subset of high risk industries such as juice and seafood Hazard Analysis Critical Control Point (HACCP), egg safety, and low acid canned foods and acidified foods. In FY 2011, 26 states received additional funding through the food contract to support the Manufactured Foods Regulatory Program Standards (MFRPS) implementation with an additional 23 states receiving funding to pursue laboratory accreditation in support of MFRPS implementation. Thirty eight states are currently enrolled in MFRPS through either the food contract or the Rapid Response Team cooperative agreement. In FY 2011, FDA also increased funding to support

Retail Program Standards.

In FY 2011, FDA classified 963 Class I, 800 Class II, and 90 Class III recalls of food products. ORA monitors recalls of food products and ensures the effectiveness of the firm's recall to remove the defective product from commerce. ORA created and successfully launched a searchable FDA webpage and database for recalls in April 2011. Additionally, a process and tracking system was developed to ensure timely posting of firm recall notices on the intranet within 24 hours of receipt.

In May 2011, a new streamlined enforcement process for seizures and injunctions was implemented. The new process increases collaboration at an early stage in the process of case development, reduces paperwork by removing redundant and unnecessary documentation, removes a bias toward inaction by making the process less daunting and more collaborative, provides a mechanism for continuous improvement in case development, and shortens approval times. Overall, FDA pursued 12 injunction and 11 product seizure actions, and issued 324 warning letters alerting firms to violations of concern that require their immediate attention to correct and prevent the continued distribution of adulterated products in U.S. commerce.

Submission of accurate prior notice data for imported food shipments by industry ensures that meaningful food defense/security risk assessments can be completed by ORA. ORA initiated more than 1,050 compliance enforcement cases, taken in conjunction with CBP, where registration information was lacking and the inadequate prior notice data was so egregious that it restricted ORA's ability to perform meaningful risk assessments. At the request of ORA in 2011, CBP issued Letters of Reprimand to two import filers for failure to transmit accurate prior notice data relating to the importation of food products.

In support of the President's Transparency Initiative, ORA started posting the most common inspection observations of objectionable conditions or practices that are found during inspections as well as a searchable database of inspected facilities with FDA inspection classifications. This website premiered in May 2011 and included data for FY 2009 and FY 2010 inspections. This effort provides the public and regulated industry with more information about company practices that may jeopardize public health, as well as identifies companies that comply with the law.

With cross agency collaboration, FDA initiated and implemented a strategy to monitor the marketplace conducting undercover purchases and investigations as part of the "Operation Shady Supplement." The strategy emphasizes the development of criminal cases against distributors of tainted supplements by OCI. Additionally, FDA safeguarded the U.S. marketplace from unsafe dietary supplements by collaborating internationally with Canada's Competition Bureau and issuing warning letters to U.S. firms marketing dietary supplements in the U.S. and Canada on the internet and Facebook with unapproved disease claims.

In May 2011, FDA implemented two new enforcement authorities under FSMA, both effective in July 2011. The first allows FDA to administratively detain food that it has reason to believe is adulterated or misbranded. The products are kept out of the marketplace while FDA determines whether an enforcement action, such as seizure or injunction against distribution of the product in commerce, is necessary. FDA used this authority multiple times in 2011.

The second authority provides FDA with more information about imports and allows for risk-based targeted examinations by requiring importers of food and feed into the U.S.to inform FDA if any country has refused entry to the same product. This new data requirement also allows FDA to make better informed decisions in managing the potential risks of imported food/feed.

During FY 2011, ORA's OCI made 11 arrests, and secured 20 convictions with fines, restitutions and other monetary penalties in excess of $10 million.

A sampling of some of the specific case activity that led to these positive public health outcomes are as follows:

Misbranded products - Distribution of cheese contaminated with salmonella and E. coli – In July 2011, a Miami company and its owners were sentenced after being convicted of conspiracy and smuggling for selling imported cheese found to contain salmonella and E. coli. The cheese had been detained by FDA and was facing further examination under FDA orders for destruction after the contamination was uncovered. The husband and wife owners were sentenced to 27 months and 40 months in prison, respectively after being found guilty in a May 2011 trial.

Product tampering - **Sentencing for tampering with salsa at restaurant** – In February 2011, a woman was sentenced to seven years in federal prison for tampering with a consumer product by putting pesticide poison in salsa served to patrons at a restaurant in Lenexa, Kansas. In June 2011, her husband was sentenced to ten years in prison for his participation in the crime. The man and his wife devised the scheme after the husband lost his job at the restaurant. Nearly 50 individuals, from young children to senior citizens, became ill from the poisoning, which occurred in August 2009.

Misbranded and adulterated products - **New Jersey dietary supplement firms and owners found guilty of contempt** – In June 2011, two companies were found guilty of multiple counts of criminal contempt along with three owners and officials of the companies. In December 2011, the owner of the two companies was sentenced to 40 months in prison and fined $60,000. Two managers of the companies were sentenced to 34 months in prison each. Both firms were also ordered to pay criminal fines totaling $1 million. The OCI investigation uncovered two New Jersey dietary supplement and food manufacturers that were violating a March 2010 consent decree ordering the business to shut down after FDA inspections found that their products were misbranded and adulterated due to unsanitary conditions at the plant. Despite the court order, the

defendants set up new operations at a different location without first getting the required FDA approval.

Adulterated products - Florida Corporation and Owners Sentenced for Distribution of Contaminated, Imported Cheese – In December 2010, a Florida corporation and its two owners were sentenced for importing cheese from Nicaragua, which was subsequently placed on hold by FDA to determine if the cheese was adulterated. FDA testing determined the cheese contained bacteria. The defendants had already sold the 440 boxes of cheese after being notified about the detention. One owner was sentenced to 6 months confinement and 2 years probation while the other defendant received five years probation.

Promoting Efficiency

The Food Inspection Contract Program and similar contracts, grants, and cooperative agreements that ORA executes through this subprogram build an integrated food safety system designed to protect the nation's food supply and minimize consumers' exposure to adulterated and contaminated food products. FDA support for state inspections often supplements two to three state-funded food inspections, thereby increasing the reach of state food safety programs ensuring a broader network of food safety for consumers. Through these grants and cooperative agreements, FDA increases the efficiency of an integrated food safety system increasing our capabilities to respond to food incidents and outbreaks while facilitating the release of safe food products for U.S. consumers.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
214205: Number of domestic high-risk food inspections. *(Output)*	FY 2011: 7,218 Target: 6,806 (Target Exceeded)	7,435	7,435	Maintain

Improving Response and Recovery - Center Activities

FY 2012 Enacted Amount: $15,517,000 (BA: $15,053,000 / UF: $464,000)

Public Health Focus

The public health focus of *Improving Response and Recovery* is to protect American consumers from harm when foodborne illness outbreaks do occur.

FDA Food Safety Strategy

The resources in this sub-program support the *FVM Strategic Plan* goal to improve detection of and response to foodborne outbreaks and contamination incidents. FDA

responds to and evaluates foodborne outbreaks and contamination incidents across the farm-to-table continuum, in order to address emerging foodborne health risks and improve FDA activities across all sub-programs to better detect and prevent such issues in the future.

Public Health Outcome

CFSAN FY 2012 enacted program activities create a structure for FDA, other public health agencies, and industry to exchange information and expertise in real time during an outbreak of foodborne illness. These resources allow FDA to respond more effectively with rapid and targeted product tracing, as well as to more accurately identify the specific firms that are responsible for the food safety problem. CFSAN's activities also enable FDA to communicate more effectively with consumers to limit morbidity and mortality and help affected industries avoid adverse economic consequences.

Coordinated Outbreak Response and Evaluation (CORE) Network: In FY 2011, FDA launched the Coordinated Outbreak Response and Evaluation (CORE) Network. CORE was established by the FDA Foods Program to manage outbreak response, surveillance, and post-response activities related to incidents involving multiple illnesses. The CORE Network strengthens FDA's efforts to prevent, detect, investigate, respond to, and learn from incidents and outbreak by centralizing incident response management and focusing on ways to improve response time and standardize procedures and activities. The CORE Network's post response activities also provide valuable insight on ways to develop and implement more effective, prevention-focused, food safety practices and policies.

Response to *Listeria monocytogenes* in Cantaloupes: The CORE Network was critical to FDA's recent successful response to a multi-state outbreak of listeriosis associated with cantaloupes.

- In September 2011, FDA, in conjunction with the Centers for Disease Control and Prevention (CDC) and state health departments, began an investigation into the source of the contamination. FDA and its partners used sampling and causal assessments to determine where in the supply chain and under what circumstances the cantaloupe became contaminated with *Listeria monocytogenes,* as well as the specific strains involved. FDA also conducted timely and effective risk communication through the CORE Network to alert industry and the public to potential public health concerns associated with recent consumption of potentially contaminated cantaloupes.
- In October 2011, FDA released an assessment of the factors that may have contributed to the contamination of fresh, whole cantaloupe, such as sanitation of packing equipment and proper cooling and cold storage of the fruit.[8] FDA's findings regarding this particular outbreak highlighted the importance for firms to employ good agricultural and management practices in their packing facilities, as

[8] http://www.fda.gov/Food/FoodSafety/FoodborneIllness/ucm276247.htm

well as in growing fields. FDA recommended that firms employ these practices for the growing, harvesting, washing, sorting, packing, storage and transporting of fruits and vegetables sold to consumers in an unprocessed or minimally processed raw form. These results underline the importance of FDA post-response activities to strengthen the food safety system from farm-to-table.

Response to *Salmonella* Agona in Papayas: FDA worked closely with Mexico in 2011 to identify the source or sources of contamination of *Salmonella* Agona in fresh papayas entering the U.S. from Mexico and strengthen produce safety for both nations.

- FDA expanded its collaborations with counterpart agencies in the Mexican government, the National Service for Agroalimentary Public Health, Safety and Quality (SENASICA) and the Federal Commission for the Protection against Sanitary Risks (COFEPRIS), after papayas imported from Mexico were linked to approximately 100 cases of *Salmonella* Agona in 23 U.S. states in early 2011. The response effort also included CDC and state health and regulatory officials, including those in Texas and Illinois.
- Following extensive analysis of imported papayas over a three-month period from nearly all the major papaya producing regions in Mexico, FDA issued an Import Alert to deny admission of papayas from each source in Mexico unless the importer showed they were not contaminated with *Salmonella*, such as by using private laboratories to test the papayas. FDA and Mexican officials began collaborating on laboratory methodologies used in Mexico for testing fresh papayas for Salmonella.
- FDA and Mexican officials developed a long term strategy to improve produce safety. The Mexican government and papaya industry agreed to a longer range action plan that will define proper food safety procedures throughout the chain of production and distribution in Mexico and verify that the procedures are working effectively through product testing and other government oversight. Mexican officials are overseeing the industry's implementation of the action plan with FDA collaboration. This plan is a powerful example of how FDA's post-response activities allow it to better prevent future incidents of foodborne illness.

Response to Domestic and International Disasters: CFSAN's FY 2012 enacted activities also support the ability of FDA to provide emergency response after major domestic and international disasters and protect U.S. citizens from food safety adverse effects of the disasters.

- In July 2011, the FDA chemical mobile laboratory (CML) was deployed to Dauphin Island, Alabama for extended surveillance of oil residues in the Gulf of Mexico seafood. The CML deployment is a federal and state collaboration to cross-train staff on oil spill response methods and to monitor fish samples obtained from the nation's largest saltwater fishing competition for residual oil contamination from the Deepwater Horizon oil spill of 2010. Sample results continue to show that the Gulf seafood is safe for consumption.

- FDA was heavily involved in the U.S. Government's activities to assist the Government of Japan and help ensure the safety of U.S. citizens after the Japan earthquake, tsunami, and nuclear disaster in March 2011. Immediately after the earthquake and tsunami, FDA's Office of Emergency Operations activated the Incident Management Group (IMG) to oversee, coordinate, and monitor issues related to the earthquake, tsunami, and the nuclear reactor crisis. CFSAN personnel served on the IMG, providing policy-level support for issues associated with FDA-regulated products.
- As part of the response to the explosions at Fukushima nuclear facilities, FDA promptly augmented the radiation screenings at U.S. borders of food imports from Japan. FDA also issued Import Alert 99-33 regarding the importation of all milk and milk products and fresh vegetables and fruits produced or manufactured from the four Japanese prefectures of Fukushima, Ibaraki, Tochigi, and Gunma, and providing information and updates to consumers on the FDA website. FDA continues to provide public information and address requests for information from media, industry groups, and Congress, as well as other stakeholders.
- FDA and the National Oceanic and Atmospheric Administration (NOAA) developed, validated, and are using new chemical tests to detect oil residues and oil dispersants in fish, oysters, crab and shrimp following the April 2010 Deepwater Horizon Gulf Oil Spill. FDA and NOAA added a second test for residues and dispersants in addition to rigorous sensory analysis tests for contaminants when considering reopening Gulf waters to fishing to help ensure the safety of seafood being harvested from the Gulf. This test adds another layer of information, reinforcing FDA findings to date that seafood from the Gulf remains safe for consumption. CFSAN and NOAA continue to monitor and evaluate on-going and long-term effects of the Deepwater Horizon oil spill on seafood safety, preventing consumers from being exposed to contaminated seafood caused by this environmental disaster.

Response-Related Outreach and Education: CFSAN's FY 2012 enacted resources support response-related risk communication and education efforts to inform consumers of food safety issues and improve the ability of industry and regulatory partners to address incidents of foodborne contamination.

- In July 2011, FDA released the Food Related Emergency Exercise Boxed Set (FREE-B) designed to take a whole-community approach to preparedness involving cross-discipline preparedness training for large-scale incidents through regular exercise and training, evaluation and plan revision. FREE-B allows stakeholders to examine their food emergency response functions and enable them to collaborate and communicate on a variety of human- and animal-health related incidents. Target stakeholders include government regulatory and public health entities, private sector, and non-traditional partners such as first responders, emergency management and law enforcement communities. FREE-B was developed in cooperation with the CDC and USDA's Animal & Plant Health Inspection Service (APHIS) and FSIS.

- FDA created and launched a Product Recall web page in April 2011 to respond to FSMA requirements for a more consumer-friendly recall search engine. The Product Recall Page features sorting and search functions that display recall information in an easy-to-read format, which includes frequently asked questions and informative videos. FDA also provides updates on the status of certain food recalls, such as mandatory recalls under FDA's FSMA authority. The page makes it easier and quicker for stakeholders to learn about product recalls so they can take appropriate steps to protect themselves and their families. One week after the site went live, the number of subscribers for email notifications when new information is posted nearly doubled, and the list continues to increase weekly.

CFSAN'sprogram activities for *Improving Response and Recovery* also include assessing issues and obstacles that hinder inter-agency data sharing and communication, identifying data systems useful for signal detection of potential adverse events, determining how to interconnect data systems in real time, and determining how to mine data for early signal detection. CFSAN is also working to develop unified, interoperable, information-sharing data systems between federal, state, and local agencies for effective signal detection and rapid response.

Promoting Efficiency

FDA's response and recovery activities reduce costs to industry during incidents of foodborne illness or contamination. Outbreaks of foodborne illness lead to reduced productivity and detrimental economic impact for individual food firms or for entire industry sectors through the loss of consumer confidence and protracted recalls. By quickly and effectively identifying contaminated products, FDA protects American consumers by removing products from the market place, while also helping industry to recover by accurately identifying firms that are responsible for the problem foods, as well as firms not associated with the safety problem.

<u>Improving Response and Recovery</u> - Field Activities
FY 2012 Enacted Amount: $ 49,327,000 (All BA)

Public Health Focus

The globalization of the U.S. food supply, rapid and widespread distribution of food, and changes in consumer expectations create the need for a framework for food protection. Protecting the U.S. food supply requires an integrated approach for recognizing, investigating, and responding to foodborne illnesses. ORA continues its work with the states to establish new and develop further existing Rapid Response Teams (RRTs), comprised of both ORA and state inspectors.

The Reportable Food Registry (RFR) is an electronic portal to which industry, public health officials, and consumers can report when there is a reasonable probability that an article of human food will cause serious adverse health consequences or death to

humans. RFRs provide regulated industry and consumers with an immediate reporting mechanism into FDA and also supply key information that is vital for effective FDA follow up activities.

To protect consumers from foodborne pathogens and to rapidly and accurately trace and identify the sources of pathogens in the food supply, it is necessary to determine species and discriminate the pathogens isolated from food. This additional identification is needed to track pathogens to the source and origin of the food exposure whether from plant, farm, or human contamination sources.

ORA devotes resources to the prompt and efficient response to foodborne outbreaks and events. ORA continues to identify and develop new investigational resources, tools, and training programs while establishing an infrastructure that will support continued effective and efficient response. As FDA continues to move forward in meeting national food defense goals, it relies on states and counties to assist in improving preparedness and response activities. Grant and cooperative agreement funds allow states and counties to increase efficiency in the areas of response, prevention and intervention in addition to allowing for a larger pool of resources nationwide to strengthen food defense and mitigate safety issues.

Molecular techniques are available to provide additional identification and greater delineation of pathogens isolated from food products. These techniques provide evidence for rapid traceback to contamination sources. All microbiology laboratories have equipment to perform this testing and microbiologists are certified to perform this analysis. The results of these determinations inform inspections and provide evidence on source, level and extent of contamination by food borne pathogens. The focus of the activities in this area is also to deliver a timely response to an emergent threat to minimize the impact to public health.

FDA Food Safety Strategy

In the case of the Improving Response and Recovery, ORA contributes to achieving the overall FDA strategy by investigation and adoption of innovative technologies and processes to detect and investigate such events, enhancement of the Reportable Food Registry, and effective risk communications related to outbreaks and contamination incidents. ORA is able to do this by responding to issues that occur across Farm-to-Table continuum and analyzing outbreaks and lessons learned from response to improve FDA activities at the other stages.

Public Health Outcome

ORA continues to partner with public and private entities to leverage data sharing and personnel. Examples of these FDA outreach partnerships include State contracts, Food Emergency Response Network (FERN) laboratories, rapid response and state lab cooperative agreements, Bovine Spongiform Encephalopathy (BSE) contracts, Partnership for Food Protection, and 50 State Meetings. This work enables federal and

state partners to improve their systems to quickly and effectively stop an outbreak and mitigate the concern.

ORA continues to devote resources to the prompt and efficient response to foodborne outbreaks and other events associated with FDA regulated commodities. Prompt mobilization of individual resources and response teams by ORA facilitates the reduction of exposure times through early investigation initiation and the collection of samples for analysis.

As part of FDA's response to the March 2011 Japan earthquake and tsunami, FDA issued Import Alert 99-33 and Import Bulletin 99-B38 to increase surveillance of Japanese food and drug products, providing a network of coverage to ensure no radiation-contaminated product reaches U.S. consumers. As the situation developed, FDA issued revisions and updates to both the Alert and Bulletin to ensure the most appropriate coverage. Field offices conducted over 28,000 examinations and field laboratories analyzed over 1,100 samples, with no objectionable findings.

As part of FDA's response to a multi-state Salmonella Agona outbreak, FDA issued an Import Bulletin to increase surveillance of suspected food products to prevent the entry of potentially contaminated products without first being analyzed. As the situation developed, FDA revised the bulletin to ensure appropriate coverage. Eventually FDA's surveillance activities led to the issuance of a countrywide Import Alert specific to papayas from Mexico. ORA's field operations helped identify a potential source of microbiological contamination in produce, and continue to ensure that the contaminated product does not reach U.S. consumers.

Deepwater Horizon Oil Spill:

In April 2010, the Deepwater Horizon Oil Rig owned and operated by BP exploded causing release of millions of gallons of crude oil into the Gulf. FDA worked with the affected Gulf States to respond to this emergency threatening seafood safety. States closed their waters to harvesting until the oil receded. ORA developed a rapid analytical method and tested hundreds of samples to inform decisions about reopening waters to commercial fishing.

ORA continues to perform inspections, sample collections, and analyses of gulf coast seafood products to assure their safety and to support the recovery. In FY 2011, conducted 192 inspections at Gulf state seafood firms and collected 137 samples of the targeted products. ORA also deployed the Mobile Laboratory which analyzed another 1,000 seafood samples.

Phthalate Contamination of Processed Foods in Taiwan:

At the end of May 2011, the Taiwanese Food and Drug Administration shared with FDA some intelligence on uncovered adulteration of raw ingredients with phthalates which are chemicals used in the plastic industry. Phthalates were being substituted as

clouding agents in certain ingredients by various Taiwan manufacturers. Upon receipt of this information, ORA immediately mobilized its laboratories and launched a collaborative method development work force to rapidly put in place an analytical method to test samples from Taiwan. Concurrent with mobilizing its laboratories, ORA also directed its field force to start stopping and collecting imports from Taiwan suspected of being contaminated with phthalates. ORA's phthalate response continues to date with over 600 samples collected.

Promoting Efficiency

FDA improved the coordinated, rapid response among Federal, State and local partners to food-related emergencies through FDA rapid response teams to minimize the public health consequences of a food safety incident. Better coordination promotes more efficient food safety response by federal, state, and local governments through improved coordination and stronger communication during a response.

In FY 2011, FDA improved the efficiency of field analytical resources by developing new, rapid analytical methods and portable analytical tools for field use, and deploying the mobile chemistry and microbiology laboratories to perform rapid analytical work to assess product safety.

To improve FDA's ability to support response and recovery, FDA Field operations continue to evaluate new technologies that provide faster and more efficient results. ORA is currently developing portable computer applications for use in the field during inspections. These applications are designed to assist the investigator in conducting an inspection, capture data on industry compliance with specific regulations to target outreach and follow-up activities, and to improve efficiencies in preparing reports of investigations.

Performance Measures

Subprogram 4: Improving Response and Recovery

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). *(Outcome)*	FY 2011: 2,500 rad & 2,100 chem Target: 2,500 rad & 2,100 chem (Target Met)	2,500 rad & 2,100 chem	2,500 rad & 2,100 chem	Maintain

Nutrition & Labeling Strategies for Better Health - Center Activities
FY 2012 Enacted Amount: $18,270,000 (All BA)

Public Health Focus

The public health focus of *Nutrition & Labeling Strategies for Better Health* is to promote healthful dietary practices through truthful and informative labeling on packaged and other foods. Reducing the chronic disease burden of the U.S. population depends in large part on consumers having the knowledge to make wise food choices and the motivation to make those choices consistently throughout all stages of their lives.

Public Health Outcome

CFSAN'sFY 2012 enacted resources in this subprogram support this objective through the regulation of food labels and the promotion of education and research programs that support good nutrition and accurate labeling. FDA also develops new tools that permit consumers to make better food choices. These activities enable American consumers to make better use of current food labeling information to maintain health and reduce the risk of chronic disease and obesity.

Restaurant Menu and Vending Machine Labeling: CFSAN issued two proposed regulations on menu and vending machine labeling as mandated by the Nutrition Labeling of Standard Menu Items in Chain Restaurants under section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(H). Specifically, the law requires restaurants, similar retail food establishments and vending machine operators — all with 20 or more locations — to provide nutrition information for certain food items. CFSAN issued two proposed regulations in April 2011 for calorie labeling on menus and menu boards in chain restaurants and similar retail food establishments, and vending machines. The proposed regulations, when finalized, will give consumers consistent and easy-to-understand nutrition information, making it easier for them to choose healthier options that can help fight obesity. CFSAN is seeking public comment and plans to issue the final rules in early 2012.

Reduced Sodium Intake: Excess sodium is a contributory factor in the development of hypertension, which is a major risk factor for heart disease and stroke. Current data and expert analysis indicate that moderate reductions in sodium intake can prevent tens of thousands of deaths and many more related illnesses and can substantially reduce public health costs. FDA recognizes ongoing efforts by a number of members of the restaurant and packaged food industries to reduce sodium and appreciates the complexities of reducing sodium in foods.

As part of the HHS Million Hearts campaign, an initiative launched in September 2011 that aims to prevent one million heart attacks and strokes over the next five years, CFSAN conducted several activities to help consumers improve their heart health through reduced sodium intake.

- In September 2011, FDA established a public docket to obtain comments, data, and evidence relevant to the dietary intake of sodium, as well as current and emerging approaches designed to promote sodium reduction.

- In November 2011, CFSAN participated in a joint public meeting with USDA and CDC entitled, "Approaches to Reducing Sodium Consumption." The meeting provided a forum for the partnership to hear directly from outside interested persons and to foster an inclusive and productive dialogue among all interested persons involved in reducing sodium intake.

FDA is using the results of these activities to continue to support consumers in reducing their sodium intake and improve their health.

Labeling Activities: CFSAN's FY 2012 enacted resources were used to support several regulatory activities to help ensure that food labels were truthful and not misleading.

- CFSAN notified 17 food manufacturers that the labeling for 22 of their food products violated the Federal Food, Drug, and Cosmetic Act. The violations cited in the warning letters include unauthorized health claims, unauthorized nutrient content claims, and unauthorized use of terms such as "healthy," and others that have strict, regulatory definitions.

- CFSAN created and recorded a food labeling training webinar and video for FDA foreign post staff to use as a tool when aiding foreign food manufacturers on labeling their products for import into the U.S.

- CFSAN completed the Spanish translation of the Food Labeling Guide, a comprehensive booklet that explains FDA's food labeling requirements.

- CFSAN jointly sponsored with USDA a delegation to Ghana, Africa to conduct a week-long training on U.S. food labeling requirements to foreign manufacturers.

Gluten Allergy Labeling: For individuals with celiac disease, the only way to prevent harmful health effects is to adhere to a life-long diet free of gluten. In 2011, CFSAN conducted the following actions involving accurate gluten labeling of food products:

- Conducted and peer-reviewed a safety assessment of gluten exposure in individuals with celiac disease, to provide further data on a possible alternative approach to identifying a specific gluten threshold level as one of the criteria to define "gluten-free." FDA had previously issued a proposed rule in 2007 on gluten-free food labeling that used an analytical methods-based approach to propose less than 20 parts per million gluten as one of the criteria to define the term "gluten-free."

- Published a *Federal Register* notice in August 2011, reopening the comment period on the Agency's proposed rule on "gluten-free" food labeling. This notice announced the availability of the Agency's safety assessment on gluten exposure in individuals with celiac disease and solicits public comment on the safety assessment and a number of issues related to defining the term "gluten-free" in a final rule. After FDA reviews and considers the comments, the Agency intends to issue, by the end of fiscal year 2012, a final rule that defines "gluten-free" for labeling food products, including dietary supplements.

Education and Outreach to Promote Healthy Diets: CFSAN conducts several education and outreach efforts to promote healthful choices that reduce the risk of chronic disease and obesity.

- With the Cartoon Network, maintains a Nutrition Label education program called SPOT THE BLOCK, with a focus on "tweens" — children ages 9-13 — aimed at building awareness of the nutrition label and label reading skills and to make healthy food choices. Evaluation of the program shows that it is effective in getting children to respond to the messages, particularly to perceive the importance of knowing the serving sizes of the food that they eat. In addition to this effort, CFSAN also released the video "Kids 'n Fiber," to provide tips on how to incorporate fiber in a child's diet. These programs result in over 80 million web and media impressions annually, providing nutrition-focused outreach and education to both adolescents and their parents across the nation.

- CFSAN implemented a Nutrition Label Education Campaign for seniors. CFSAN developed educational tools for seniors to improve their understanding and use of the Nutrition Facts label to manage healthy eating and prevent disease. CFSAN also developed web-based materials and brochures to be distributed to seniors through senior centers and area Offices on Aging.

- CFSAN partnered with NSTA to develop a web-based tutorial on nutrition for middle and high school science teachers. The program recruits 200 teachers nationwide who commit to completing and using the tutorial, and tracks the gains in teacher understanding of good nutrition choices through pre-assessment and post-assessment.

Promoting Efficiency

Treatment of chronic diseases accounts for approximately 75 percent of the $2 trillion that America spends on health care each year.[9] This is twelve percent of the U.S. Gross Domestic Product. According to data from the CDC, chronic diseases cause seven out of ten deaths each year.[10] Poor nutrition contributes to chronic diseases such as hypertension, heart disease and stroke. CDC data indicate that more than 30 percent of the American adult population, or 60 million people, are obese.[11] FDA's Nutrition and Labeling sub-program helps reduce the burden on the U.S. economy associated with obesity and chronic diseases by helping consumers maintain health, reduce the risk of chronic disease and obesity, and make informed decisions to improve their diet and health.

[9] Anderson G. Chronic conditions: making the case for ongoing care. Baltimore, MD: John Hopkins University; 2004.
[10] http://www.cdc.gov/chronicdisease/overview/index.htm
[11] http://www.cdc.gov/obesity/data/trends.html

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
212408: The number of American consumers who recognize dietary steps that they can take to reduce their risk of chronic disease. (Outcome)	NA	NA	Set baseline	NA

Reinventing Cosmetics Safety - Center Activities

FY 2012 Enacted Amount: $8,033,000 (All BA)

Public Health Focus

The focus of *Reinventing Cosmetics Safety* is to protect the public health through FDA oversight of the safety of cosmetics marketed in the United States, whether manufactured domestically or imported. The cosmetic industry is changing rapidly as manufacturing becomes more global, technologies become increasingly sophisticated, and cosmetic ingredients become more complex. The industry-named category of products that straddles the line between cosmetics and drugs —"cosmeceuticals" — and products containing ingredients produced through nanotechnology present particular scientific and public health challenges.

Public Health Outcome

CFSAN 'sFY 2012 enacted resources support product surveys and laboratory investigations and allow FDA to maintain systems for voluntary cosmetic product registrations. CFSAN's cosmetics program activities include the evaluation of adverse event reports and consumer complaints. Information from these sources is essential for risk-based approaches to postmarket monitoring of cosmetic products, and outreach, inspection, and enforcement activities.

Cosmetics Safety Outreach: CFSAN conducted outreach in 2011 to improve public and industry understanding of potential cosmetic product issues and gather information on ways in which FDA can improve cosmetics safety.

- FDA developed and distributed material on why and how to report cosmetic related adverse events to CFSAN, presenting this information at several major professional conferences. This outreach effort supports FDA's ability to conduct surveillance on cosmetics products safety by helping to improve reporting frequency and quality.

- CFSAN held a public meeting with stakeholders in Washington, D.C., in November 2011, on microbiological safety issues relevant to cosmetic products. The purpose of the meeting was to provide stakeholders an opportunity to share information with FDA, consumers, and industry on variety of cosmetic microbiological safety issues. These included: the microbiological testing of cosmetics; the identity and prevalence of microorganisms that pose specific health risks in products; product and packaging characteristics that affect microbial growth and risk of infection; consumer subpopulations that may be at greater risk of infection from cosmetic products; and adverse events associated with microbial contamination of cosmetics. The meeting provided valuable information on issue areas where FDA guidance may help ensure the safety of American consumers from potential cosmetic safety issues.

Cosmetics Regulatory Science: CFSAN also conducted several cosmetics laboratory investigations in FY 2011 to inform its regulatory activities.

- CFSAN developed and validated an analytical method for determining peptides in skin matrices and cosmetic products. This method provides valuable information on skin absorption of cosmetic products.
- CFSAN developed and validated an analytical method for determining para-Phenylenediamine, a contact allergen, in cosmetic products and formaldehyde in fingernail products. Formaldehyde is a known human carcinogen and exposure is a significant consideration for consumer health and safety.

Nanotechnology: CFSAN's FY 2012 enacted activities also support several efforts focused on nanotechnology. Cosmetics represent one of the fastest growing areas for the application of this emerging technology. Nanoparticles used in cosmetic ingredients may result in products with different chemical or physical properties that may pose different safety issues. These cosmetics program activities support collaborative laboratory investigations with the University of Maryland on various types of nanoparticles and the potential health hazards when used in cosmetics. CFSAN drafted guidance for industry and other stakeholders on the use of nanoscale materials in cosmetics, as part of the Agency's focus on nanotechnology safety. The guidance is expected to be published in 2012.

Promoting Efficiency

FDA administers the Voluntary Cosmetic Registration Program (VCRP), which benefits consumers and industry. Through VCRP, cosmetic manufacturers can register their manufacturing sites and submit ingredient listings for the products they market. This information allows FDA to stay abreast of the current cosmetics marketplace and guides FDA efforts to protect the health of consumers.

Information from VCRP is also critical to the activities of the Cosmetic Ingredient Review (CIR) group, an industry-sponsored organization that assesses the safety of cosmetic ingredients and makes the findings available to the public. FDA participates in the CIR,

providing information about the types of products in which cosmetic ingredients are used and their frequency of use. The CIR uses this information to assess the safety of specific ingredients and in setting overall review priorities. This safety review program facilitates more efficient product development by providing industry with information on ingredients to avoid or limit to achieve new and safer products, which is a significant benefit to industry and consumers.

Reinventing Cosmetics Safety - Field Activities
FY 2012 Enacted Amount: $3,253,000 (All BA)

ORA provides coverage of the rapidly expanding import and domestic cosmetic programs by conducting inspections and sample analyses on products in order to prevent unsafe cosmetics or ingredients from reaching consumers in the United States.

In FY 2011, ORA issued 67 notices identifying modifications to cosmetics-related Import Alerts encompassing violations related to microbiological contamination and non-permitted or undeclared color additives (this is not inclusive of all cosmetic-related program areas). These actions were a result of ORA import surveillance collections and testing of regulated cosmetic products at the time they were offered for import into the U.S. These notices serve to provide increased coverage at the border to assure these products are not available to the U.S. consumer.

Performance Measures

The following table lists the performance measures associated with this subprogram.

Measure	Most Recent Result / Target for Recent Result	FY 2012 Target	FY 2013 Target	FY 2013 +/- FY 2012
214208: Number of American consumers who are aware of FDA's Adverse Event Reporting System for Cosmetics. (Outcome)	NA	Set baseline	+5% over baseline	+5% over baseline

Information Technology Investments – Foods Program Activities (FY 2012 Enacted Amount displayed as a non-add item: $116,708,547)

FDA modernized and enhanced its information technology (IT) infrastructure to provide a state of the art, secure technological foundation to support all FDA programs. This newly completed effort provides a foundation on which FDA may improve its capabilities and enhance its ability to perform its scientific and regulatory mission. FDA's agency-wide costs associated with the operation and maintenance of this shared IT infrastructure includes two data centers, telecommunication networks, IT security and help desk functions. In addition, each center and office has program specific IT systems and is supported by enterprise systems ranging from improving the premarket review process for all regulated products to post-market surveillance, including adverse event detection, and future scientific computing capabilities This common infrastructure

facilitates consolidation and meets E.O.13514 related to energy efficiency, HHS and OMB mandates with respect to green computing, cloud computing, and virtualization.

To fulfill its essential mission of protecting public health, FDA must receive, process, store, and analyze information about the products it regulates and make decisions quickly and credibly based on reliable and accessible information. FY 2012 enacted IT resources allow FDA to better protect American consumers from food safety risk across the farm to table continuum. IT systems enable FDA to conduct signal detection, identify science-based risk factors, and develop models to improve and support outbreak prevention and mitigation, compliance activities and regulatory decision making.

IT modernization efforts likewise enable the FDA to better identify and more quickly respond to foodborne outbreaks and contamination incidents. For example, FDA FY 2012 enacted resources provide tools for rapid analysis that improve FDA's ability to protect the nation's food supply from known and unknown pathogens and contaminants In FY 2011, FDA quadrupled its genomic sequencing capability, in turn, reducing food sample analysis response timeframes from weeks to days. FY 2012 enacted resources will also allow the FDA to increase its storage network to manage the exponential growth in new data produced by these cutting-edge, rapid detection tools.

FY 2012 enacted IT resources also improve the overall effectiveness of the FDA Foods Program by enabling data-driven, risk-based decision-making in addressing public health issues. For example, due to the globalization of the U.S. food supply and increased responsibility under FSMA to ensure that imported food is as safe as that produced domestically, amounts of imported foods, FDA has invested in the processing of importing data and developed automated compliance targeting assessment algorithms using a screening tool known as Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT). PREDICT has improved the FDA's ability to prevent the entry of adulterated, misbranded, or otherwise violative goods and expedite the entry of non-violative goods. Likewise, the Reportable Food Registry (RFR) enables mandatory electronic reporting of adulterated and potentially harmful foods by industry, thus facilitating the earlier detection and removal of adulterated foods from the market place. Continued investment in RFR enables the FDA to provide data for effective risk communication related to these types of incidents and to decrease response time to foodborne outbreaks and contamination incidents.

As a result, FY 2012 enacted IT resources are critical to the success of FDA efforts to adopt a more proactive strategy for food safety. IT investments allow FDA to capitalize on pre- and post-market data, scientific research, and current event information, thereby improving the identification of threats to the public health, and ultimately reducing the incidence of foodborne illness outbreaks.

Five Year Funding Table with FTE Totals

The following table displays funding and full time equivalent (FTE) staff levels from FY 2008 through FY 2012 for the Foods Program.

Fiscal Year	Program Level	Budget Authority	User Fees	Program Level FTE
FY 2008 Actual	$507,797,000	$507,797,000	$0	2,614
FY 2009 Actual	$712,769,000	$712,769,000	$0	2,995
FY 2010 Actual	$783,178,000	$783,178,000	$0	3,387
FY 2011 Actual	$836,244,000	$836,244,000	$0	3,605
FY 2012 Enacted	$882,747,000	$866,061,000	$16,686,000	3,757

Summary of the Budget Request

The FY 2013 budget request for the Foods Program is $1,083,939,000. This amount is an increase of $201,192,000 above the FY 2012 Enacted Level. CFSAN's amount in this request is $367,622,000, supporting 1,082 FTE. The Field amount is $716,317,000, supporting 2,965 FTE.

The FY 2012 enacted funding for the Foods Program is $882,747,000, which includes $264,760,000 for Foods Program Center activities and $617,987,000 for the Foods Program Field activities.

FDA's Foods Program executes its regulatory responsibilities through five sub-programs: 1) Prioritizing Prevention, 2) Strengthening Surveillance and Enforcement, 3) Improving Response and Recovery, 4) Nutrition & Labeling Strategies for Better Health, and 5) Reinventing Cosmetics Safety.

FY 2012 enacted funding allows the Foods Program to implement the Administration's vision of a new, integrated, and prevention-focused food safety system to better protect the American public. The initiatives proposed under the requested budget will allow FDA to achieve HHS and Presidential public health priorities, including the requirements of the landmark FDA Food Safety Modernization Act (FSMA). These resources support FDA public health objectives of preventing illnesses caused by contaminated foods, protecting consumers, and supporting improved health and nutrition.

Funding the FY 2013 request will allow the Foods Program to protect public health by:

- assessing potential safety problems

- ensuring that manufacturers use appropriate control measures to reduce or eliminate contaminants in foods
- taking steps to remove products from the market that violate safety standards
- continuing the development and implementation of an integrated national food safety system building on uniform standards.

The initiatives proposed under the FY 2013 budget request support HHS, FDA and Presidential public health priorities and mission-critical program activities to Transform Food Safety and Nutrition. The FY 2013 funding request will greatly enhance domestic and global efforts to substantially reduce foodborne illnesses caused by contamination of the food supply for years to come.

Budget Request

Data Consolidation and IT Savings
(Total Program: -$7,651,000)

The request for $855,239,000 in total budget authority for the Foods Program also reflects data consolidation and IT savings reduction of -$7,651,000 for FY 2013. The Center's portion of these savings is -$2,335,000 and the Field's portion is -$5,316,000.

The Foods Program will achieve savings by:

- Reducing the number of redundant IT devices. This initiative, with the requisite health and safety exception, will reduce device costs, including hardware, software licenses, and maintenance and also reduce helpdesk and desktop support costs
- FDA's consolidation of the operations support of the two primary FDA data centers to one contractor compared to the two distinct service providers presently in place. This consolidation will achieve operational and process efficiencies through the elimination of redundant contractor management teams, and achieve economies of scale in the 24/7/365 network and server operations.
- delaying or forgoing planned investments related to data transmission improvement infrastructure
- maximizing the use of local storage and minimize peak hour transmission of large files across the network to reduce the data transmission volume of the existing telecommunication infrastructure.

Rent Absorption
(Total Program: -$3,759,000)

The request for $855,239,000 in total budget authority for the Foods Program also reflects the rent absorptions of -$3,759,000 for FY 2013. The Center's portion of these savings is -$950,000 and the Field's portion is -$2,809,000.

Center Activities:

CFSAN will reduce investment in regulatory science infrastructure, including necessary equipment and technology upgrades. Lack of investment in regulatory science infrastructure will impede CFSAN's ability to develop and implement science-based standards and provide essential science-based information to industry to develop preventive controls. These tools are essential for reducing potential hazards before they harm American consumers by allowing FDA to better detect both known and unknown pathogens and better understand potential hazards. Additionally, CFSAN will be unable to keep pace with new, science-based, rapid-detection technologies and rapid risk assessments necessary to improve the effectiveness and efficiency of FDA response to foodborne outbreaks.

Field Activities:

The Field Foods Program will cut operating costs to cover the rent absorption.

The Pay Increase (Commissioned Corps), Data Consolidation and IT Savings, and Rent Absorption affect all sub-programs.

Prioritizing Prevention

Center Activities – FY 2012 Enacted Amount: $79,075,000 (All BA)

FY 2013 Increase above FY 2012 Enacted Level: (+$41,852,000 / 50 FTE)

2013 Initiatives:

Transforming Food Safety and Nutrition: Regulation and Guidance - FSMA Sections 101, 103, 104, 105, 106, 110, 204, 209, 210, 405 (UF +$26,846,000 / 35 FTE)

Foodborne illnesses linked to known causes are preventable if the parties involved in today's global food chain can be held accountable for implementing appropriate preventive measures at each step of the process where control of hazards is necessary. Regulations and guidance are important prevention-focused tools that guide food industry efforts and provide the framework for accountability for meeting appropriate standards called for by FSMA. The more successful the food system is in implementing

appropriate preventive measures in the production, processing, transportation, and preparation of foods, the safer the nation's food supply will be.

CFSAN will conduct the following activities with the user fee resources in this subprogram:

- develop science-based regulations and guidance documents to support industry adoption of preventive controls and produce safety standards that take account of the wide diversity of food production and processing operations
- develop performance standards for food hazards and review food safety plans for food facilities as needed
- hold public meetings and engage in extensive outreach, dialogue, and other efforts with the food industry to ensure that FDA regulations, standards and guidance documents are practical as well as protective; provide education to growers, industry, and consumers
- provide education and technical assistance to industry in the form of uniform hazard analysis standards, scientifically sound, risk-based controls for food and dietary ingredients, and model food safety plans for food and feed facilities
- encourage the use of cooperative compliance models through outreach to industry and the scientific community during the rulemaking process.
- provide training to industry, and federal and state regulatory partners in support of implementation of new FSMA standards.

Transforming Food Safety and Nutrition: Import Safety - FSMA Sections 201, 211, 301-308 (UF +$10,548,000 / 8 FTE)

This investment will support comprehensive, prevention-focused import food and feed safety programs that will place more responsibility on those in the food supply chain – food and feed manufacturers, processors, packers, distributors, transporters, and importers – to ensure that the food and feed imported into the United States are safe and meet regulatory requirements. In a globalized and increasingly complex world, reliance on a regulatory body to perform thorough supply chain verification through examination and/or sampling of commodities at the time they are offered for import is infeasible and cannot provide adequate assurance of product safety. To ensure that imported products are as safe as those produced domestically, FDA will develop and implement a variety of approaches to imported food safety, including foreign supplier verification, accredited third party certification, comparability assessments, and improved foreign inspections.

CFSAN will conduct the following activities with the user fee resources in this subprogram:

- continue to conduct foreign food safety system comparability assessments to determine which countries have comparable food safety systems or robust commodity-specific export programs
- conduct initial assessments of recognized third party certification programs
- establish programs to recognize and accredit third party certification programs for food imports, followed by periodic systems audits
- develop and expand partnerships with other public health agencies to execute international outreach, training, capacity building, and technical support, and develop materials and information packets to support foreign inspections.

Proposed User Fee: Food Contact Substances Notification Program Fee (UF +$4,458,000 / 7 FTE)

With resources funded by user fees, CFSAN will expand and develop the Food Contact Notification Program to ensure stable, long-term viability of the current food contact substances authorization process. This stability and predictability is to the advantage of consumers, FDA, and the regulated industry because the FCN process is simpler, more efficient, and requires fewer resources than the alternative food additive petition process. The user fees will also support continued development and updates of industry guidance, including guidance to address emerging regulatory challenges associated with the use of nanotechnology and endocrine active chemicals in food contact materials. In addition, user fee funds will enable CFSAN to continue its preeminence in the regulatory science applicable to food contact materials, benefiting both U.S. consumers and industry.

Field Activities – FY 2012 Enacted Amount: $111,373,000 (All BA)

FY 2013 Increase above FY 2012 Enacted Level: (+$49,360,000 / 39 FTEs)

2013 Initiatives:

Transforming Food Safety and Nutrition: Implementing the FDA Food Safety Modernization Act – Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 (UF +$9,360,000 / 39 FTEs)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide uniform coverage and safety oversight of the food supply. ORA will conduct the following activities with the resources in this subprogram:

- hire two FTE with user fees to develop and administer ORA food certification programs for inspections, investigators, and analysts at FDA and its regulatory partners to ensure that all parties are performing to the national standard

- hire three FTE to ensure programmatic objectives and implementation of the Integrated Food Safety System are coordinated and provide support for the governance structure
- hire 25 FTE with user fees to perform program oversight through ORA audits of regulatory and public health partners to measure their performance against FDA program standards
- hire six FTE with user fees to serve as field state liaisons to assist the States with implementation of the Manufactured Food Regulatory Program Standards (MFRPS)
- hire three FTE with user fees to develop and validate certification testing instruments.

Transforming Food Safety: Regulations and Guidance (UF +$40,000,000 / 0 FTE)

To implement and enforce preventive controls in food processing facilities, FDA will train more than 9,600 ORA inspections personnel, as well as a portion of FDA's state, tribal, and territorial regulatory partners, in preventive controls inspections and enforcement methods to ensure that inspection personnel are prepared to conduct sound, effective inspections in the new preventive controls framework. FDA will expand the program to also train foreign regulators, third party, and industry representatives in preventive controls and other FSMA policies.

Strengthening Surveillance and Enforcement – A. Strengthening Surveillance

Center Activities – FY 2012 Enacted Amount: $118,770,000 (All BA)

FY 2013 Increase above FY 2012 Enacted Level: (+$31,919,000 / 23 FTE)

2013 Initiatives:

Transforming Food Safety and Nutrition: Integrated Food Safety System - FSMA Sections 201, 202, 203, 204, 205, 209, 210 (UF +$11,423,000 / 15 FTE)

With these resources, FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments in state, local, tribal and territorial regulatory and public health partners. These investments will provide more uniform coverage and safety oversight of the food and feed supply.

CFSAN will conduct the following activities with the user fee resources in this subprogram:

- evaluate and implement new methods, training, fit-for-purpose method extension, and new instruments to expand laboratory capacity for the integrated national food safety system
- expand the current FDA proficiency testing program to better target food safety and food defense concerns in support of the FSMA mandate for laboratory accreditation
- update Foods Program methods validation manuals, such as the Bacteriological Analytical Manual (BAM), the Pesticide Analytical Manual (PAM), and the Elemental Analysis Manual (EAM), through the provision of web services, the coordination of methods development and validation, International Standards Organization (ISO) Board membership, and funding proficiency testing needs for participating partner labs.

Transforming Food Safety and Nutrition: Risk Analysis - FSMA Sections 103, 104, 105, 106, 201, 204, 301, 203, 303, 306 (UF +$11,621,000 / 3 FTE)

FDA will improve and implement data-driven risk ranking and prioritization tools to inform regulatory, compliance, and resource allocation decision-making critical to the successful implementation of FDA's FSMA responsibilities. Currently, FDA is largely limited to reliance on epidemiological approaches to understand and prevent foodborne outbreaks. As a result of this initiative, FDA will be able to rank and prioritize food safety concerns, and identify how to best apply limited Agency resources to achieve the best possible public health outcomes.

CFSAN will conduct the following activities with the user fee resources in this subprogram:

- improve and implement data-driven risk ranking and prioritization tools, such as iRisk and iPrioritize, to inform regulatory, compliance, and resource allocation decision-making critical to the successful implementation of FDA FSMA responsibilities
- adapt risk analysis tools for use by the public and industry to improve understanding and precision of risk evaluation of FDA-regulated commodities and associated hazards.

Transforming Food Safety: Science for Food Safety – Critical Capacity for Implementation of FSMA (UF +$8,875,000 / 5 FTE)

Scientific research and analysis provide the basis for developing appropriate regulations and guidance. This investment will allow FDA to establish food safety standards that are based on the latest scientific developments and that address hazards from farm-to-table. FDA will also apply research results to improve response speed and effectiveness.

CFSAN will conduct the following activities with the user fee resources in this subprogram:

- develop innovative methods and tools to validate preventive controls and hazard analysis and to better detect pathogens and chemical contamination in foods, such as *Salmonella*, *E. coli* O157, *Listeria monocytogenes*, Hepatitis A, viruses, and toxins
- develop and deploy new chemical detection technologies to better identify and address chemical hazards in the food supply both before and after illness occurs
- develop new methods and platforms for rapid fingerprinting of food pathogens, along with methods for determining the geographic origin of contaminated food samples, to support rapid analysis in both laboratories and the field with high throughput and at low cost.

Field Activities – FY 2012 Enacted Amount: $286,953,000 (All BA)

FY 2013 Increase above FY 2012 Enacted Level: (+$12,961,000 / 51 FTEs)
FY 2013 increase for proposed user fees (International Courier): (+721,000; 3 FTE)

2013 Initiatives:

Transforming Food Safety: Import Safety – FSMA Sections 201, 301, 302, 305, 306 and 307 (UF +$11,040,000 / 43 FTE)

This investment will allow FDA to continue to administer the Foreign Supplier Verification Program (FSVP) and conduct import verification inspections using risk-based strategies to target inspections and rapid field tests to better target sampling at the border. FDA will establish and implement procedures for electronic verification of importers compliance status with FSVP. This electronic verification will allow FDA to make appropriate admissibility determinations for foods offered for import.

- hire 43 FTE to support the FSVP, which is a subcomponent of the Import Accountability Verification Program

Transforming Food Safety: Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 (UF +$1,200,000 / 5 FTE)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide uniform coverage and safety oversight of the food supply. ORA will conduct the following activities with the resources in this subprogram:

- hire four FTE to serve as Official Establishment Inventory (OEI) Coordinators for the field
- hire one FTE with user fees to serve as Scientific Coordinators. This resource will support the states as FDA moves to national standards for laboratories.

Strengthening Surveillance and Enforcement – B. Strengthening Enforcement

Center Activities – FY 2012 Enacted Amount: $25,095,000 (All BA)

FY 2013 Increase above FY 2012 Enacted Level: (+$10,823,000 / 28 FTE)
2013 Initiatives:

Transforming Food Safety and Nutrition: Import Safety - FSMA Sections 201, 211, 301-308 (UF +$4,325,000 / 12 FTE)

To ensure that imported products are as safe as those produced domestically, FDA will develop and implement a variety of approaches to imported food safety, including foreign supplier verification, accredited third party certification, comparability assessments, and improved foreign inspections.

CFSAN will conduct the following activities with the user fee resources in this subprogram:

- plan and evaluate foreign inspections conducted to prevent illness or injury from possibly unsafe or contaminated foods including foreign firm notification to request permission to conduct inspections, inspection reports review, development of decision support systems, and management of follow-up compliance actions.
- continue to develop and expand the infrastructure and processes to enable timely enforcement action and follow-up compliance actions related to foreign inspection
- conduct testing and analysis of foreign samples to inform compliance cases and entry decisions.

Transforming Food Safety and Nutrition: Domestic Inspections - FSMA Section 201 (UF +$6,498,000 / 16 FTE)

FSMA recognizes that preventive control standards can only improve food safety to the extent that producers and processors comply with the standards. Therefore, domestic inspection initiatives are essential for FDA to provide oversight, ensure compliance, and respond effectively when problems emerge. Inspections are essential for holding the industry accountable for their responsibility to produce safe products.

CFSAN will conduct the following activities with the user fee resources in this subprogram:

- improve enforcement tools and processes in order to successfully manage the increasing number of safety-related compliance cases expected in association with increased frequency of domestic inspections
- modernize and expand compliance programs to reflect changes introduced by FSMA, including planning inspection work, analyzing trends of violative firms,

and identifying firms who are non-compliant or who have not registered as a food establishment with the Agency to ensure sufficient oversight and monitoring needed to protect the public health.

These activities are new investments for FDA in FY 2013.

Field Activities – FY 2012 Enacted Amount: $167,081,000 (BA: $ 150,859,000 / UF: $16,222,000)

FY 2013 Increase above FY 2012 Enacted Level: (+$39,164,000 / 32 FTE)
FY 2013 increase for Current Law User Fees (Food Reinspection): (+$309,000 / 0 FTE)
FY 2013 increase for Current Law User Fees (Recall): (+$426,000 / 0 FTE)

2013 Initiatives:

Transforming Food Safety: Import Safety – FSMA Sections 201, 301, 305, 306 and 307 (UF +$10,204,000 / 30 FTE)

With this investment FDA will continue to conduct foreign food safety system comparability assessments to determine which countries have comparable food safety systems or robust commodity-specific export programs. FDA will also increase staff to conduct accredited third party certification performance audits and assessments. FDA will work with foreign regulatory counterparts on an individual and/or coalition basis to improve information sharing, outreach to the private sector, and other collaboration to facilitate implementation of the import safety provisions of FSMA. Concurrently, FDA will use budget authority to expand critical enforcement and compliance support for foreign food facility inspections. These activities include planning inspections, notifying foreign firms to request permission to conduct inspections, reviewing inspection reports, developing decision support systems, and managing follow-up on compliance actions.

- hire 15 FTE to conduct audits of foreign regulatory bodies
- hire 15 FTE to perform performance assessments and audits of the Third-Party Certification Recognition/Accreditation Program

Transforming Food Safety: Integrated Food Safety System – FSMA Sections 201, 205, 209 and 210 (UF +$15,225,000 / 0 FTE)

With this investment FDA will continue to develop and implement an integrated national food safety system built on uniform regulatory program standards, strong oversight of the food supply, and sustainable multi-year infrastructure investments to provide more uniform coverage and safety oversight of the food supply. ORA will conduct the following activities with the resources in this subprogram:

- provide funding to federal, state, local, territorial and tribal regulatory and public health partners in the form of at least ten states grants, contracts, cooperative agreements or inter-agency agreement between federal agencies. Ten of the state grants, contracts, cooperative agreements or inter-agency agreements

between federal agencies would be funded with budget authority and ten would be funded with user fees.

- improve, strengthen, and standardize regulatory activities among all partners to ensure consistent oversight, application, and enforcement of food safety laws, and regulations.

Transforming Food Safety: Domestic Inspections and Technology for Greater Efficiency – FSMA Sections 201 (UF +$13,000,000 / 2 FTE)

FSMA recognizes that preventive control standards can only improve food safety to the extent that producers and processors comply with the standards. Therefore, domestic inspection initiatives are essential for FDA to provide oversight, ensure compliance, and respond effectively when problems emerge. Inspections are essential to hold industry accountable for their responsibility to produce safe products.

The resources for domestic inspections will allow FDA to modernize inspection approaches and compliance programs and improve FDA food safety enforcement tools and processes to support the prevention strategy mandated by FSMA. This is essential in order to achieve the most public health value from FDA inspection and compliance programs and successfully manage the increasing number of safety-related compliance cases expected in association with increased frequency of domestic inspections.

This investment will also allow FDA to acquire new technologies to improve the efficiency and effectiveness of inspections. Remote Access Devices will allow field staff to examine shipments and complete all required electronic submissions for data entry on site, print labels for samples collected, and complete collection reports and all necessary documentation. In addition, expedited review, examination, and sampling of products will result in a decrease in the time needed to complete an inspection by providing field staff with the ability to perform the majority of work on site. The advanced technology will provide opportunities for enhanced targeting of shipments, resulting in greater assurance in the safety of commodities physically examined by FDA.

Improving Response and Recovery

Center Activities – FY 2012 Enacted Amount: $15,517,000 (All BA)

FY 2013 Increase above FY 2012 Enacted Level: (+$9,342,000 / 6 FTE)
FY 2013 Increase for Current Law User Fees (Recall): (+$21,000 / 0 FTE)

2013 Initiatives:

Transforming Food Safety and Nutrition: Planning and Response - FSMA Sections 202, 204, 205, 206 (UF +$9,342,000 / 6 FTE)

This initiative will enable FDA to respond effectively and reduce illness and deaths when food safety problems emerge and affect the public, despite preventive controls, as well as learn from outbreaks and other food safety incidents to inform future prevention

efforts. This funding will also support FDA's ability to enforce mandatory recall authority to respond immediately when a food company fails to recall unsafe food voluntarily. CFSAN will conduct the following activities with the user fee resources in this subprogram:

- work with government and industry partners to develop new traceback tools and systems unifying information from regulatory partners and private sources
- expand support for responsive food recall processing and case management to continue to improve the ability of FDA to execute this authority under FSMA
- enhance existing systems and expand tools and databases for surveillance, outbreak detection, outbreak response and investigation, and post-response activities under the Coordinated Outbreak Response and Evaluation (CORE) team
- enhance the Reportable Foods Registry to better support FSMA food recall requirements.

Field Activities – FY 2012 Enacted Amount: $49,327,000 (All BA)

FY 2013 Increase above FY 2012 Enacted Level: (+$240,000 / 1 FTE)

2013 Initiatives:

Transforming Food Safety: Planning and Response – FSMA Sections 201, 301, 302, 305, 306 and 307 (UF +$240,000 / 1 FTE)

This investment will allow FDA to respond effectively and reduce adverse public health impacts when food safety problems emerge and threaten the health of the American public. This investment will also improve FDA's ability to learn from outbreaks and other food safety incidents, and thereby improve future prevention efforts. This funding will also support FDA's ability to enforce mandatory recall authority and respond immediately when a food company fails to voluntarily recall unsafe food.

FDA will work with government and industry partners to develop new traceback tools and new systems that unify information received from FDA regulatory partners and private

- fund one FTE to develop and implement traceback procedures

Reinventing Cosmetics Safety

Center Activities – FY 2012 Enacted Amount: $8,033,000 (All BA)

FY 2013 Increase above FY 2012 Enacted Level: (+$12,012,000 / 42 FTE)
2013 Initiatives:

Proposed User Fee: Cosmetic Safety User Fee (UF +$12,012,000 / 42 FTE)

CFSAN will use user fee funds to establish a Mandatory Cosmetic Registration Program (MCRP) that will require all domestic and foreign cosmetic labelers marketing products in the U.S. to register their establishments and products with FDA. CFSAN will provide information gathered from the complete listing of marketed cosmetic products and their ingredients to industry to assist them in their safety evaluations and product modifications. The user fees will also enable CFSAN to meaningfully participate in international harmonization efforts for cosmetic standards. As a result, FDA will be better positioned to fulfill its public health mission and will promote greater safety and understanding of cosmetic products being used regularly by consumers.

Field Activities – FY 2012 Enacted Amount: $3,253,000 (All BA)

FY 2013 Increase above FY 2012Enacted Level: (+$4,320,000 / 18 FTEs)
FY 2013 increase for Proposed User Fee- Cosmetic User Fee: (+$4,320,000 / 18 FTE)

FDA is proposing new legislative authority to require all domestic and foreign cosmetic labelers marketing products in the U.S. to register their establishments and list their products with FDA and pay an annual fee, with a sliding scale of fees for certain small businesses. Registration will provide both FDA and industry with a better understanding of the cosmetic products being marketed. The user fee investment in the Cosmetics Program will better position FDA to fulfill its public health mission and will promote greater safety and understanding of products being used regularly by consumers.

Without this initiative, FDA will continue to lack vital information necessary to provide domestic regulatory oversight and leadership, as well as leadership in international harmonization efforts. Moreover, without knowledge of the full range of cosmetic products and ingredients being marketed in the United States and the facilities that are involved in providing such products to American consumers, including foreign firms, FDA is hampered in its ability to effectively protect American consumers from unsafe products.

This initiative provides long-term, stable funding for the FDA Cosmetics Program, which in turn ensures better public health protection for all Americans. The initiative will also better enable FDA to obtain critical data about the industry in an increasingly global marketplace, and provide increased public confidence and continued U.S. leadership in international harmonization efforts. These benefits are largely realized by industry in terms of increased sales and lower costs.

Combined Field Activities – ORA
Program Activity Data

Field Foods Program Activity Data (PAD)

Field Foods Program Workload and Outputs	FY 2011 Actual	FY 2012 Estimate	FY 2013 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	***10,517***	***12,517***	***12,517***
Domestic Food Safety Program Inspections	7,385	**Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.**	**Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.**
Imported and Domestic Cheese Program Inspections	305		
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	483		
Domestic Fish & Fishery Products (HACCP) Inspections	1,752		
Import (Seafood Program Including HACCP) Inspections	353		
Juice HACCP Inspection Program (HACCP)	220		
Interstate Travel Sanitation (ITS) Inspections	1,088		
Domestic Field Exams/Tests	4,092	3,945	3,945
Domestic Laboratory Samples Analyzed	11,240	11,300	11,300
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS	***999*** [2]	***1,200***	***1,200*** [1]
All Foreign Inspections	999	1,200	1,200
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT INSPECTIONS	***11,516***	***13,717***	***13,717***
IMPORTS			
Import Field Exams/Tests	201,406	160,200	160,200
Import Laboratory Samples Analyzed	35,292	35,300	35,300
Import Physical Exam Subtotal	**236,698**	**195,500**	**195,500**
Import Line Decisions	10,167,887	10,616,840	11,085,616
Percent of Import Lines Physically Examined	2.33%	1.84%	1.76%
Prior Notice Security Import Reviews			
(Bioterrorism Act Mandate)	88,057	80,000	80,000
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	***9,765***	***10,523***	***10,523***
UNIQUE COUNT OF STATE PARTNERSHIPS FOOD ESTABLISHMENT INSPECTIONS	***273***	***273***	***273***
State Contract Food Safety (Non HACCP) Inspections	8,535	9,318	9,318
State Contract Domestic Seafood HACCP Inspections	1,123	1,104	1,104
State Contract Juice HACCP	93	103	103
State Contract LACF	79	68	68
State Partnership Inspections	273	273	273
State Contract Foods Funding	$19,068,458	$11,507,200	12,312,710
Number of FERN State Laboratories	19	19	19
Number of Food Safety State Laboratories	15	15	15
Annual FERN State Cooperative Agreements/Operations Funding	$18,270,000	$18,390,000	$18,490,000
Total State & Annual FERN Funding	**$37,338,458**	**$29,897,200**	**$30,802,710**
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS	***21,554***	***24,513***	***24,513***

[1] For investigators hired with FY 2013 BA funding received through the Office of International Programs (OIP) for the China Import Safety Initiative, the full performance year is FY 2015. During the full performance year (FY 2015), the FY 2013 funding increase for inspections will allow OIP to conduct an additional 135 foreign food safety inspections. Please also see the FDA Headquarters /OIP narrative for further information.

[2] The FY 2011 actual unique count of foreign inspections includes 35 OIP inspections (25 for China and 10 for India).

Combined Field Activities – ORA
Program Activity Data

Field Cosmetics Program Activity Data (PAD)

Field Cosmetics Program Workload and Outputs	FY 2011 Actual	FY 2012 Estimate	FY 2013 Estimate
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	**153**	***100***	***100***
Domestic Inspections	153	100	100
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***2***	***0***	***0***
Foreign Inspections	2	0	0
IMPORTS			
Import Field Exams/Tests	3,034	1,600	1,600
Import Laboratory Samples Analyzed	626	630	630
Import Physical Exam Subtotal	**3,660**	**2,230**	**2,230**
Import Line Decisions	2,121,088	2,389,000	2,690,751
Percent of Import Lines Physically Examined	0.17%	0.09%	0.08%
GRAND TOTAL COSMETICS ESTABLISHMENT	***155***	***100***	***100***